US009314404B2

(12) **United States Patent**
Gonzalez-Miranda et al.

(10) **Patent No.: US 9,314,404 B2**
(45) **Date of Patent: Apr. 19, 2016**

(54) **DRUG COMPOUNDING SKID AND COMPOUNDING METHOD**

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(73) Assignee: **Allergan, Inc.**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 426 days.

(21) Appl. No.: **13/848,586**

(22) Filed: **Mar. 21, 2013**

(65) **Prior Publication Data**

US 2014/0209727 A1 Jul. 31, 2014

Related U.S. Application Data

(63) Continuation-in-part of application No. 13/756,461, filed on Jan. 31, 2013, now abandoned.

(51) **Int. Cl.**

B02C 17/00	(2006.01)
A61J 3/00	(2006.01)
B02C 19/00	(2006.01)
B01F 13/10	(2006.01)

(52) **U.S. Cl.**

CPC ***A61J 3/002*** (2013.01); ***B01F 13/1022*** (2013.01); ***B01F 13/1055*** (2013.01); ***B02C 17/00*** (2013.01); ***B02C 19/0056*** (2013.01); *Y10T 137/0402* (2015.04); *Y10T 137/4266* (2015.04)

(58) **Field of Classification Search**

CPC A61J 3/00; A61J 3/002; B01F 13/1022; B01F 13/1055; Y10T 137/0402; Y10T 137/4266; B02C 19/00; B02C 19/0056; B02C 17/00

USPC 241/153, 2

See application file for complete search history.

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* cited by examiner

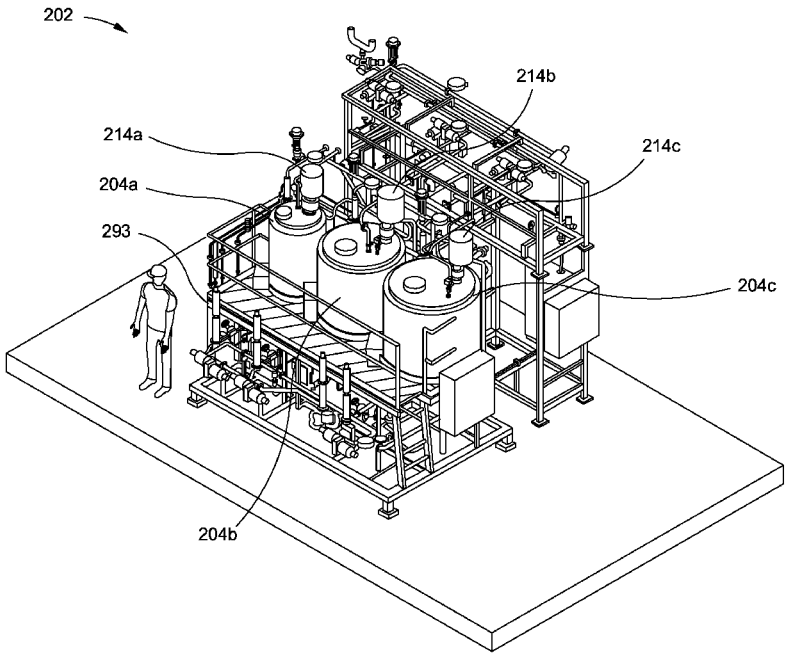
Primary Examiner — Mark Rosenbaum

(74) *Attorney, Agent, or Firm* — Joel B. German

(57) **ABSTRACT**

A drug compounding skid for sterile transfer of a compounded drug. The skid includes vessels configured to form a sterile seal of a drug contained therein. The skid may include a sterilization system, a drug transfer system, and a cleaning system. The skid may be used to perform sterile transfer of a compounded drug from the vessels to a holding tank. A skid may include a plurality of drug compounding tanks with agitation devices mounted thereto.

12 Claims, 27 Drawing Sheets



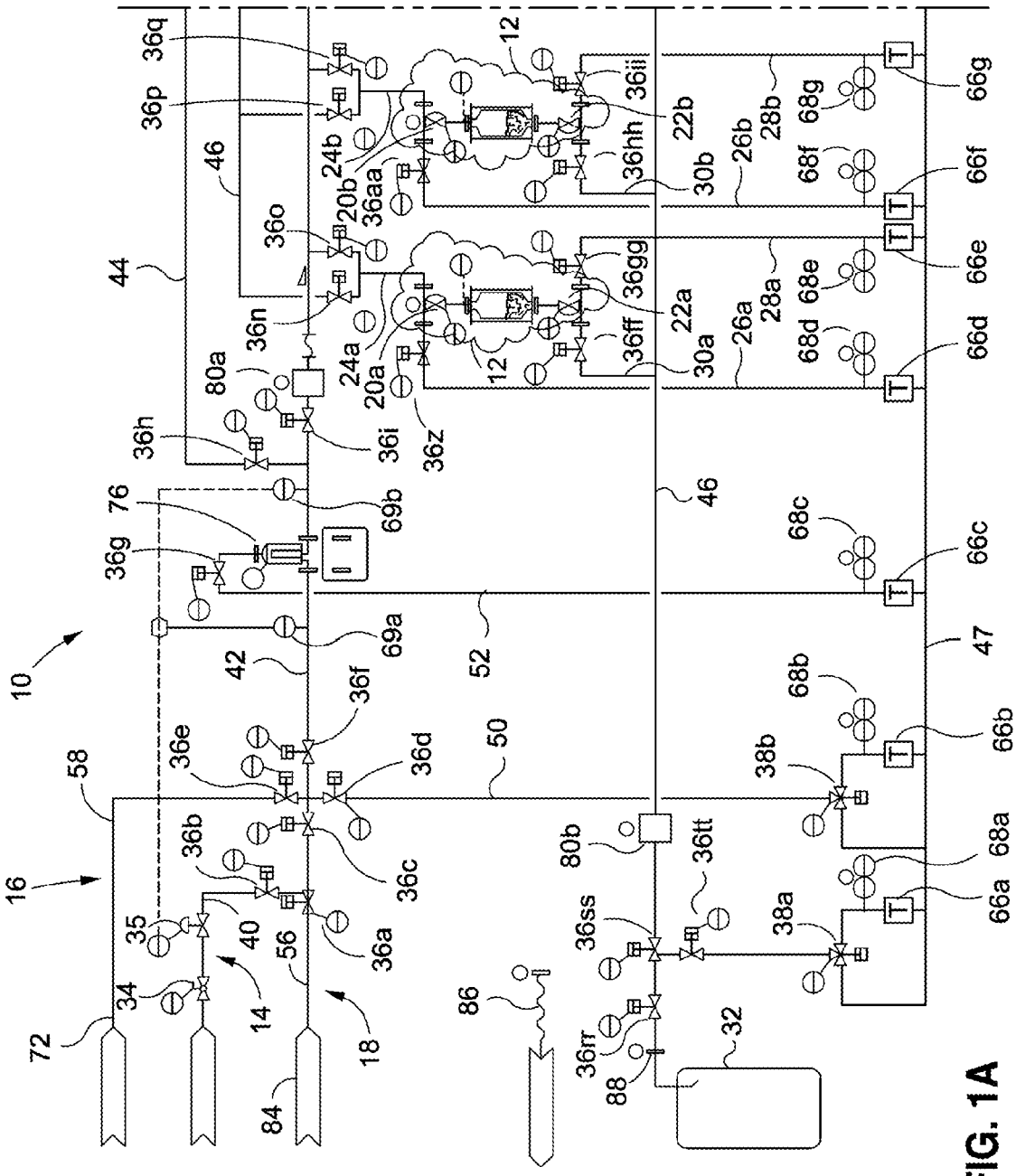
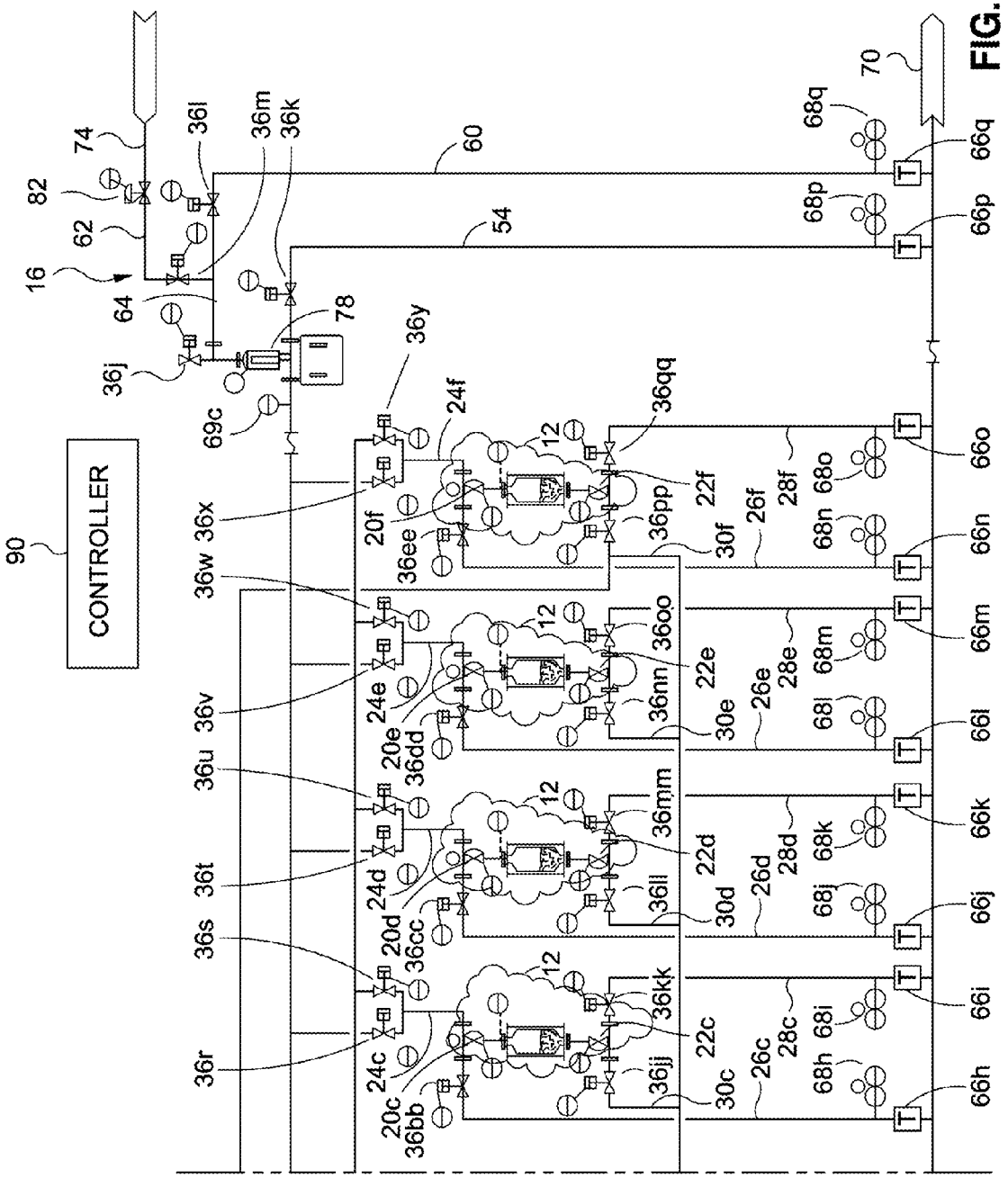


FIG. 1A

FIG. 1

FIG. 1A | FIG. 1B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22f
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36pp
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26f
28f
68o
66o
68n
66n
36x
36w
36v
36u
36t
36s
36r
24e
20e
36dd
36oo
22e
36nn
30e
26e
28e
68m
66m
68l
66l
24d
20d
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FIG. 1B

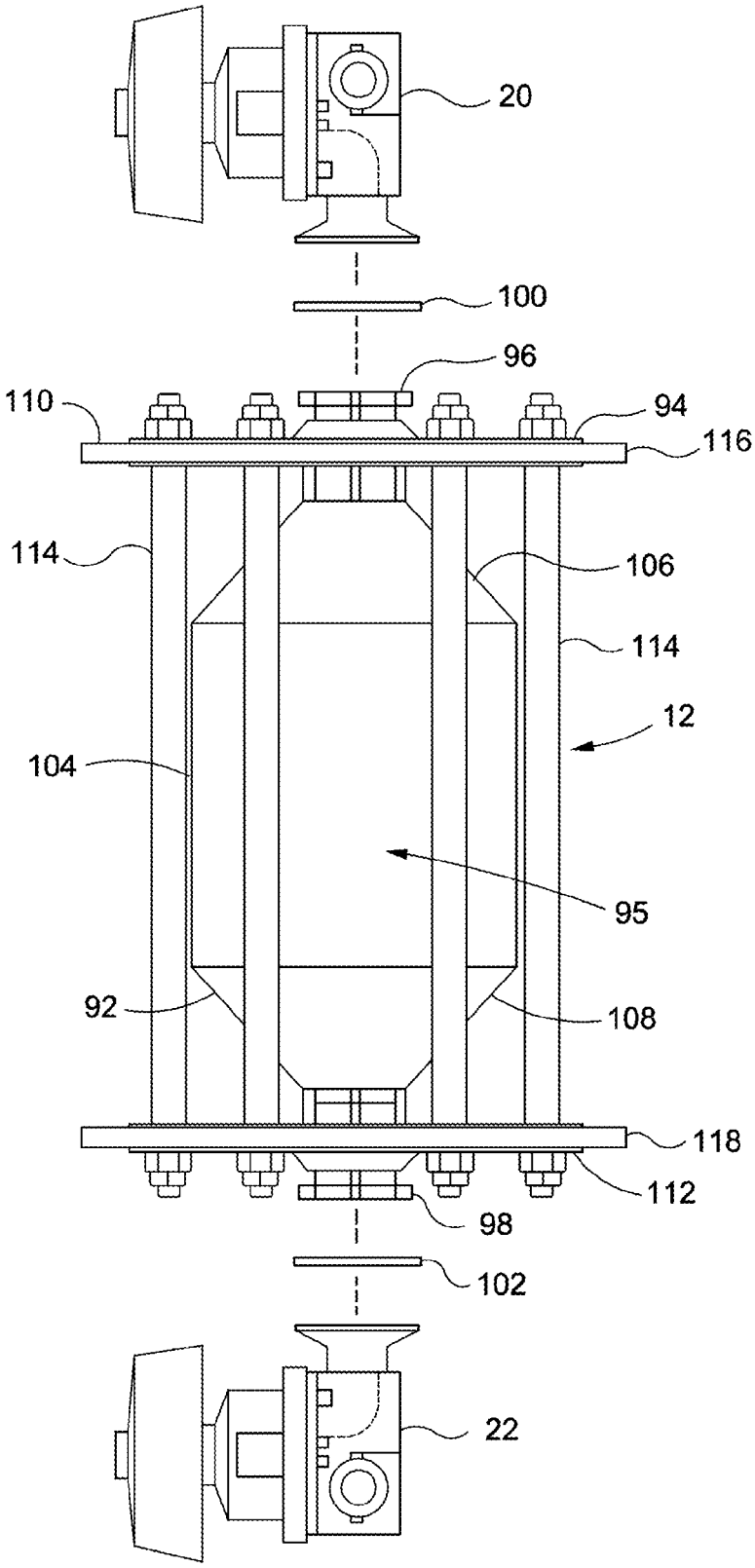

FIG. 2A

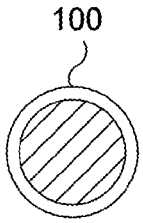

FIG. 2B

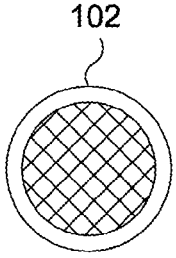

FIG. 2C

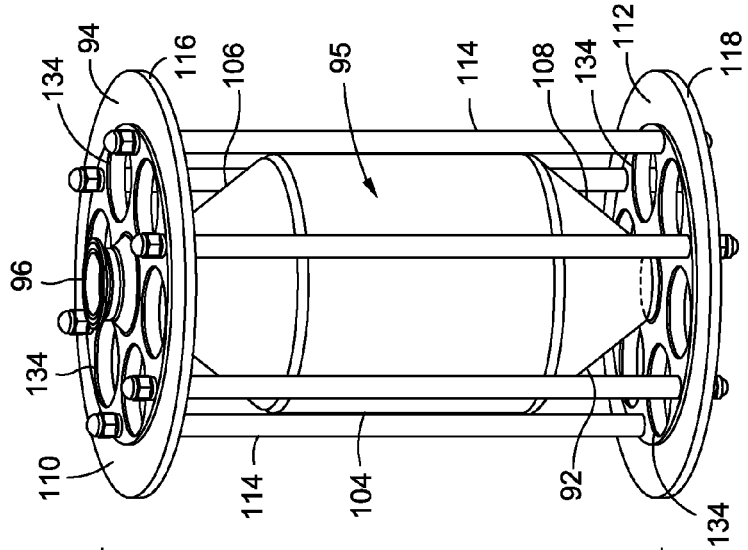

FIG. 3C

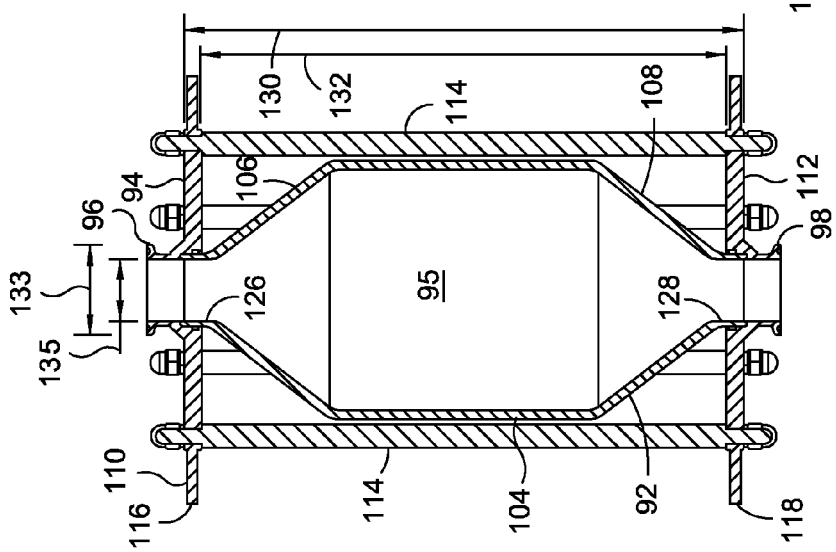

FIG. 3B

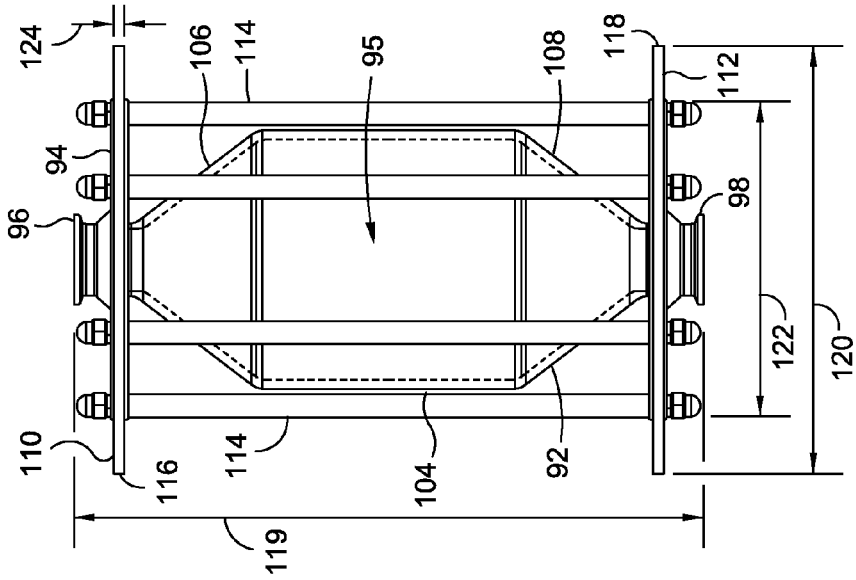

FIG. 3A

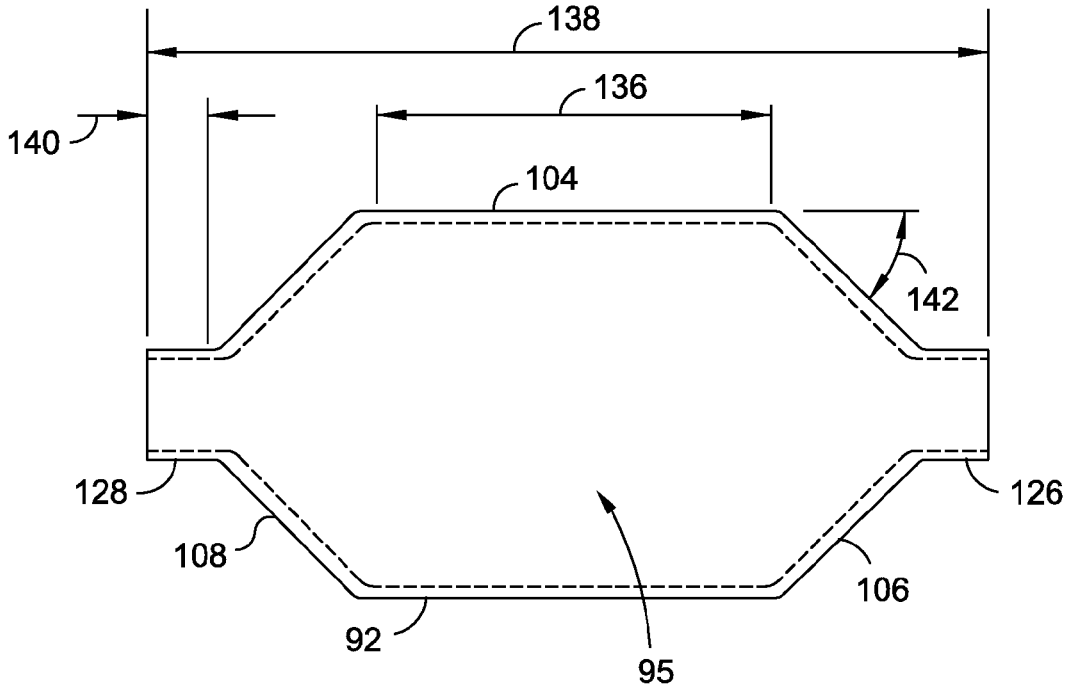
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FIG. 4A

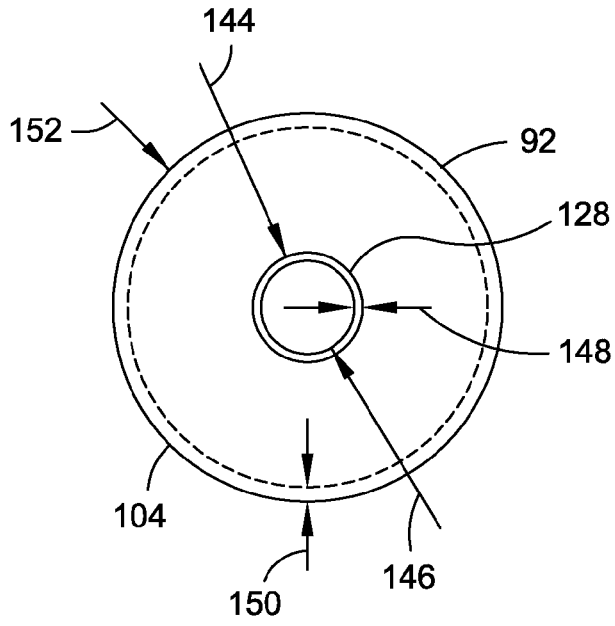
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FIG. 4B

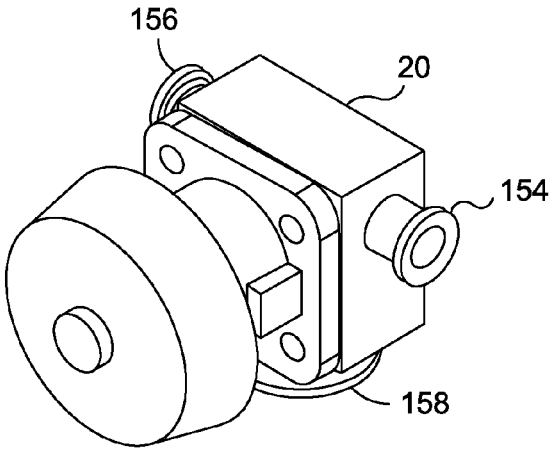

FIG. 5A

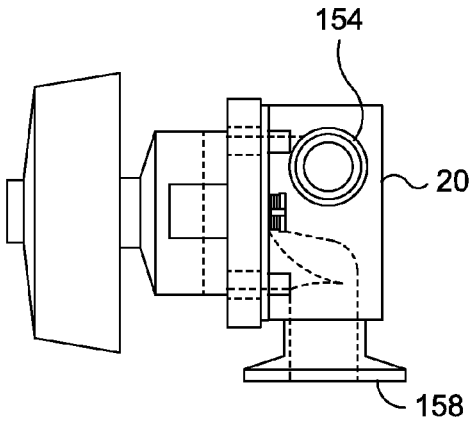

FIG. 5B

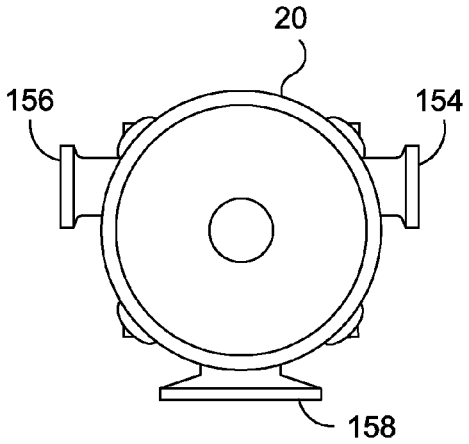

FIG. 5C

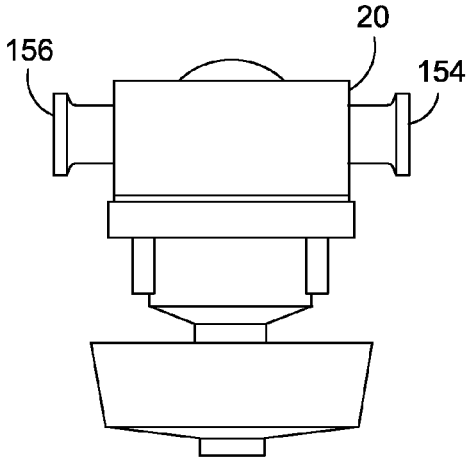

FIG. 5D

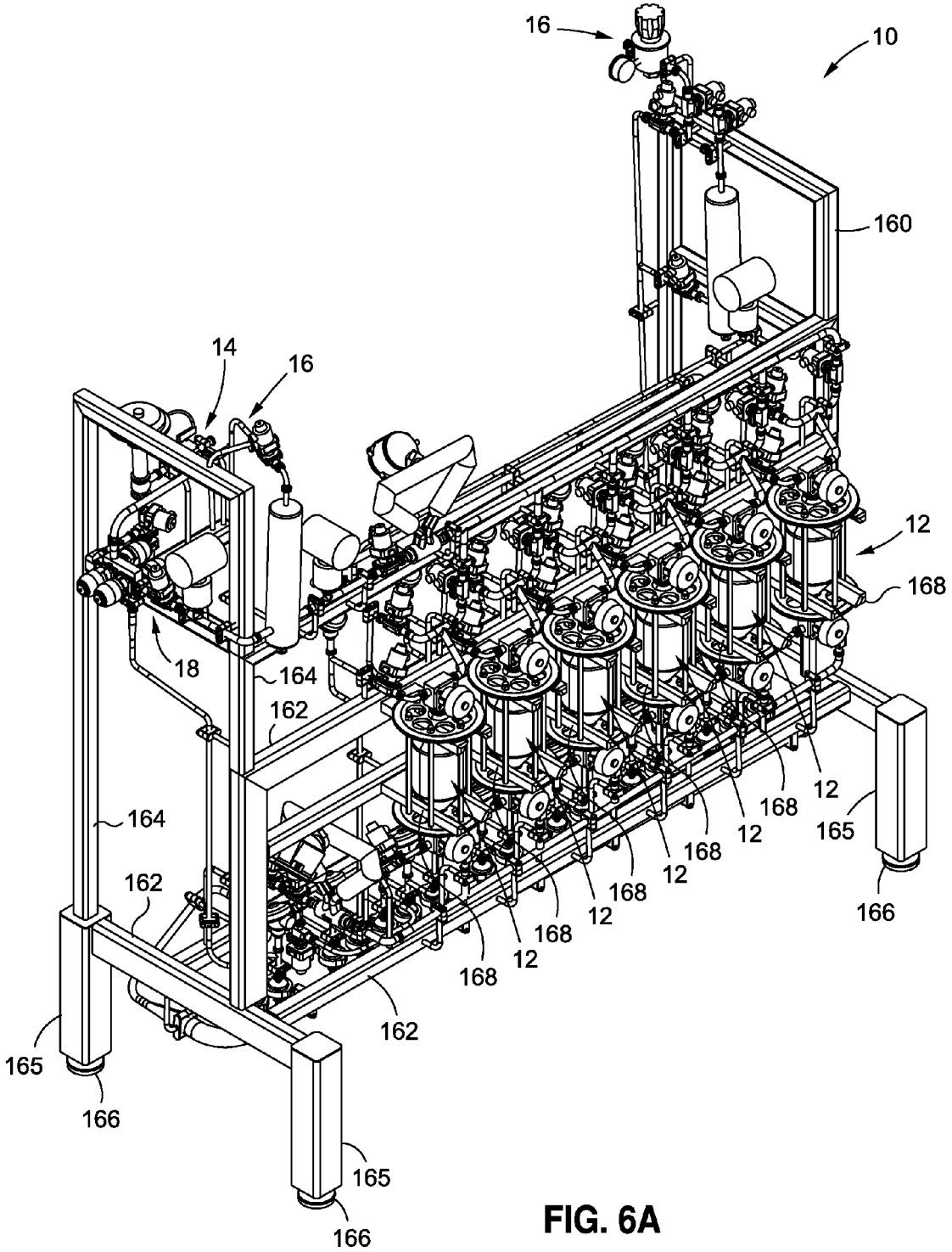
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FIG. 6A

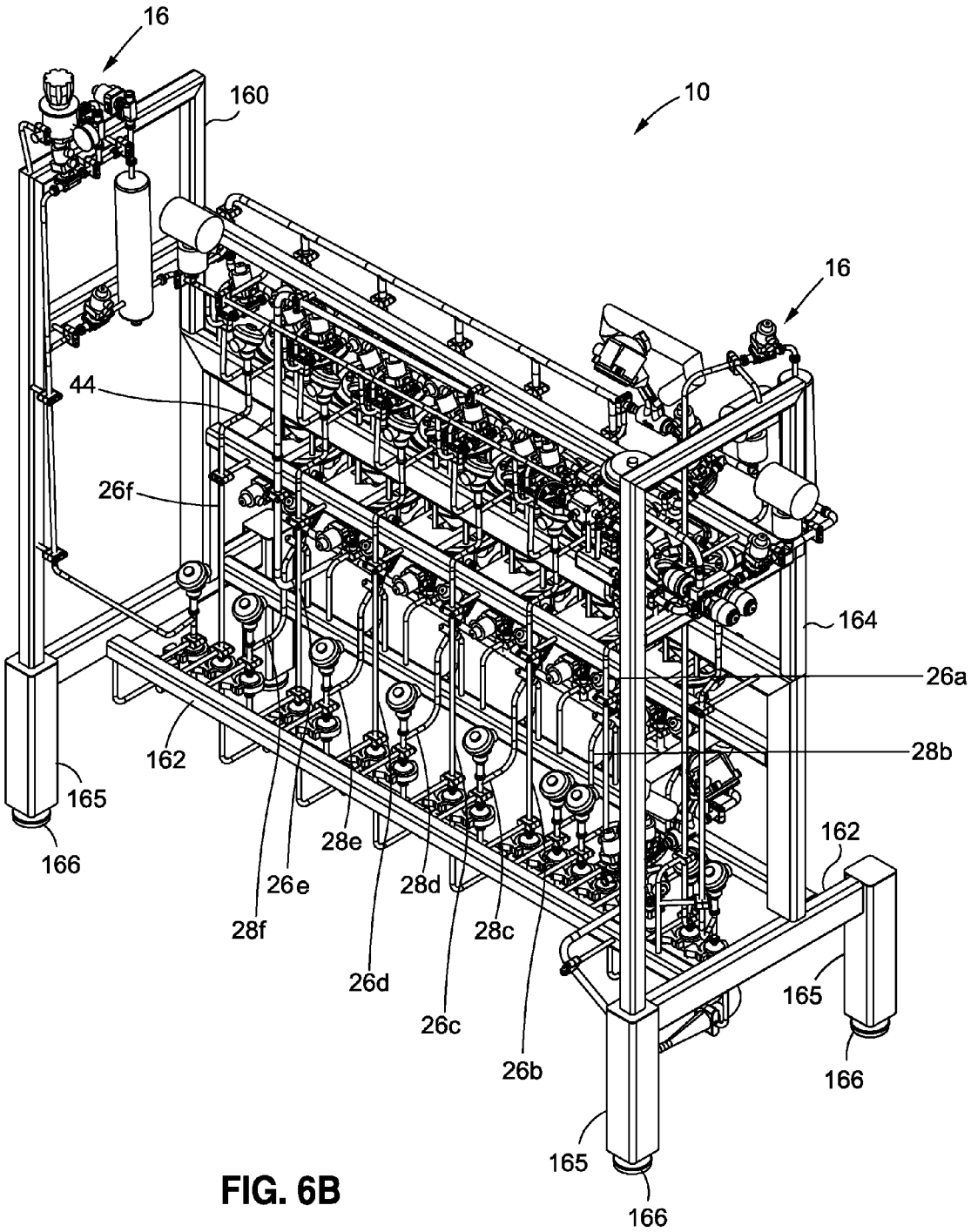
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FIG. 6B

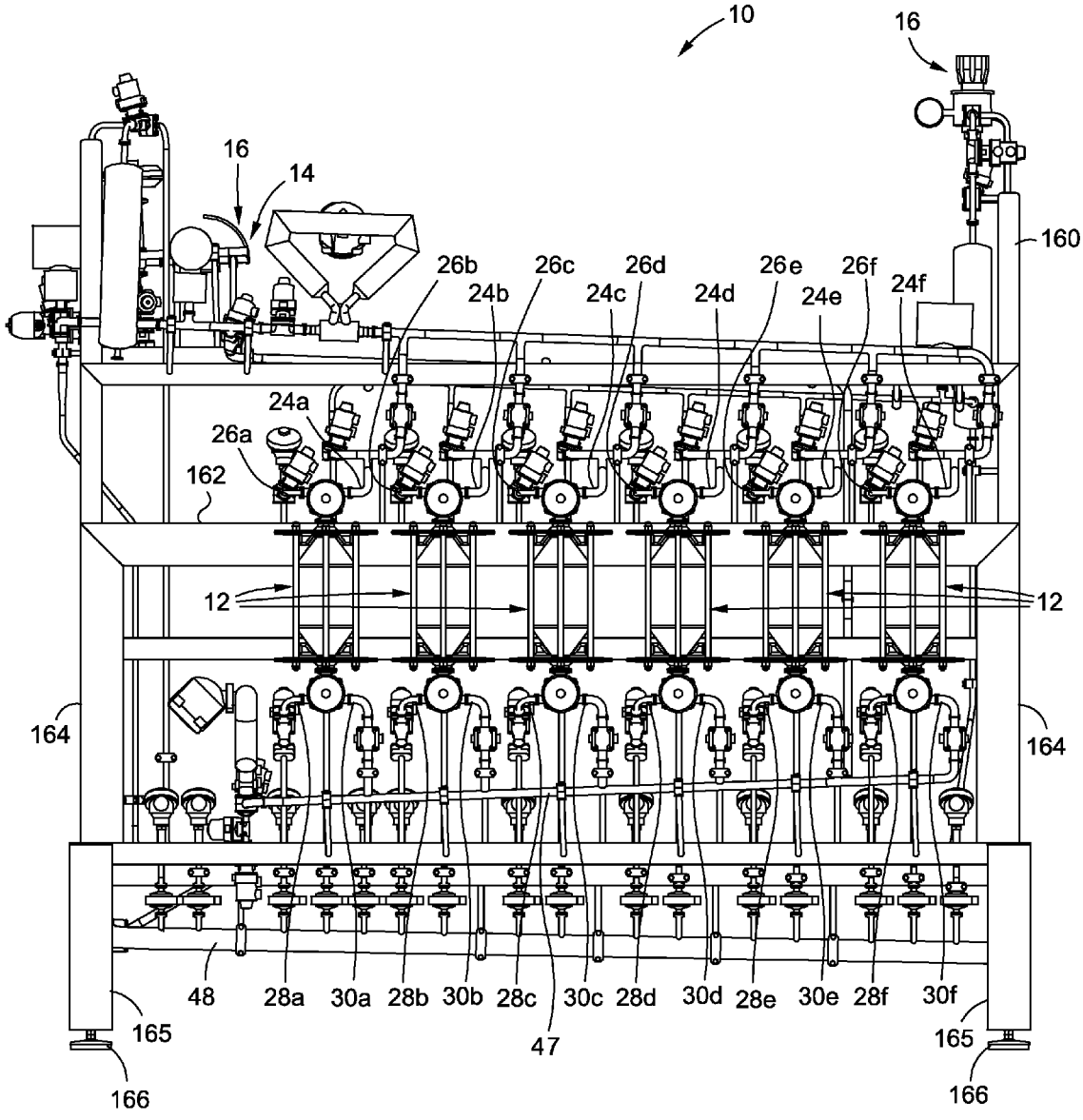
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FIG. 6C

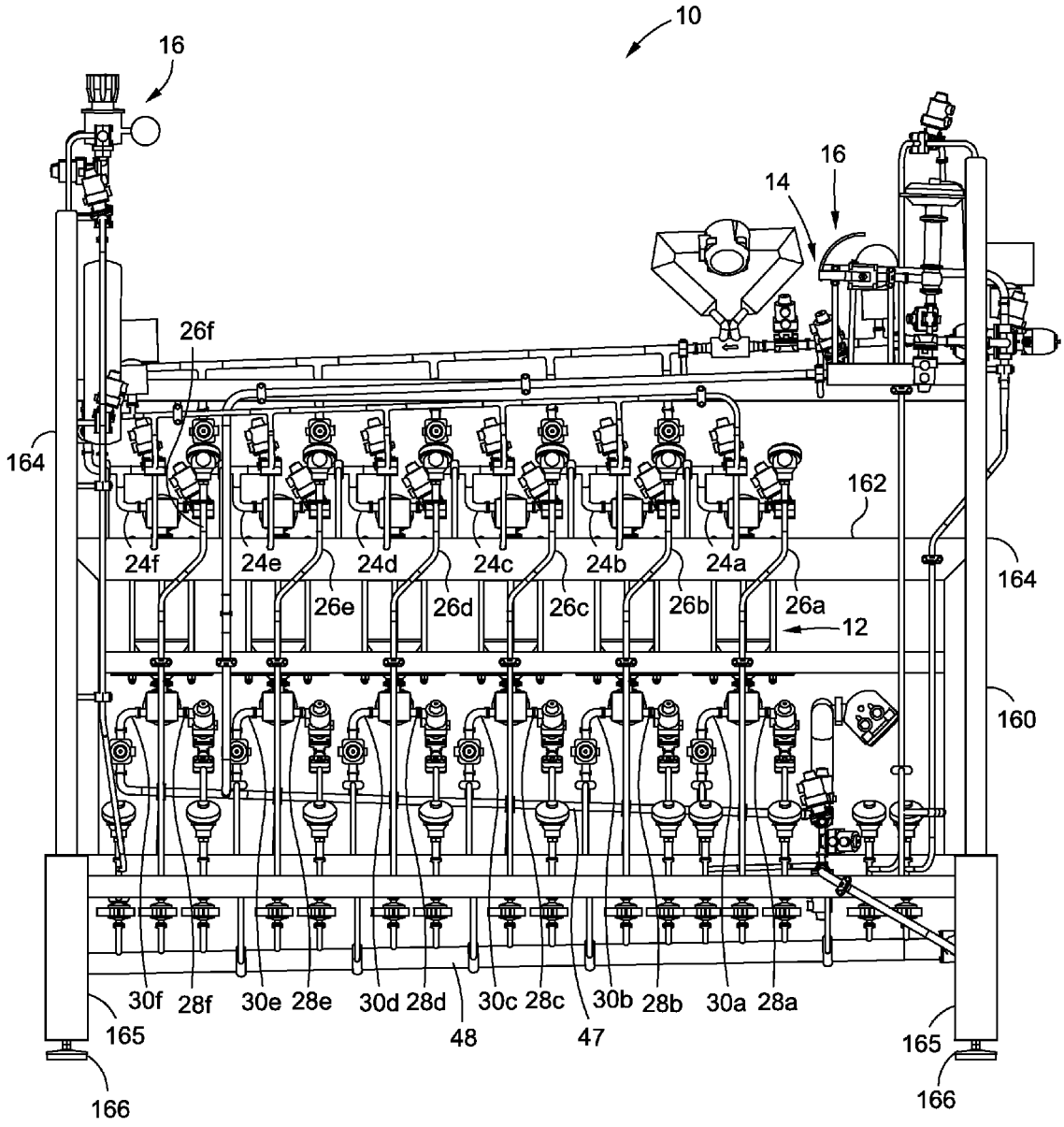
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FIG. 6D

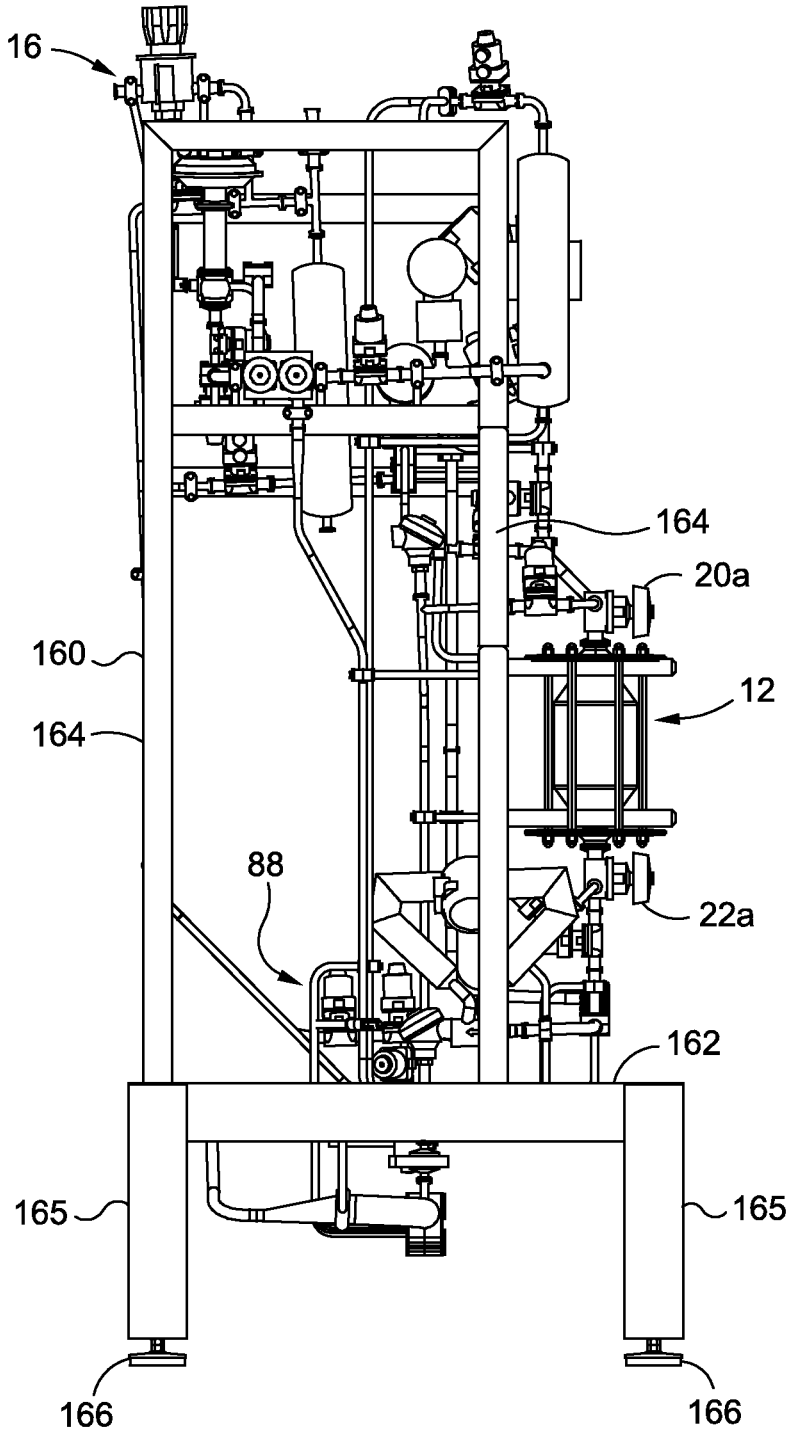
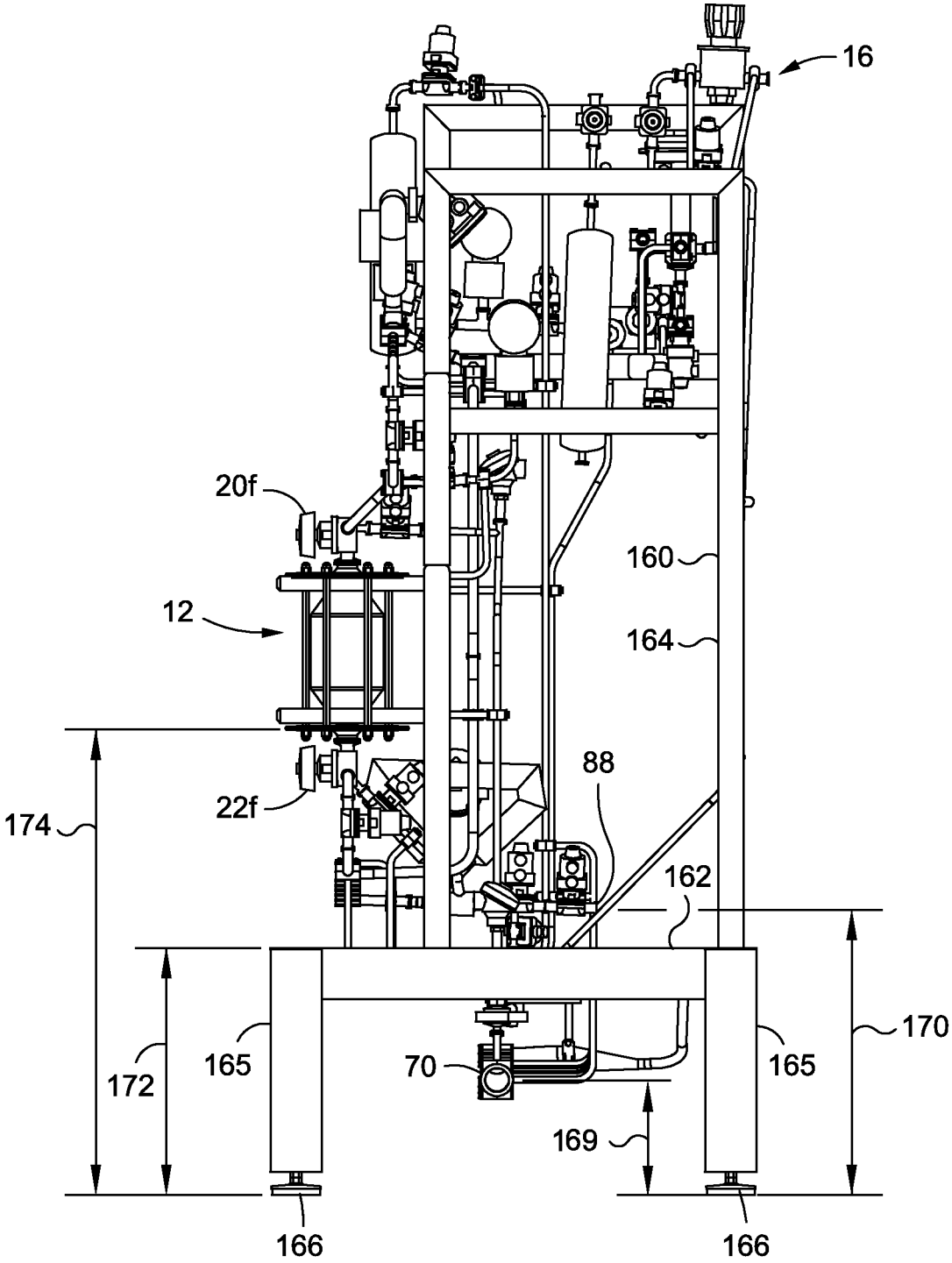


FIG. 6E



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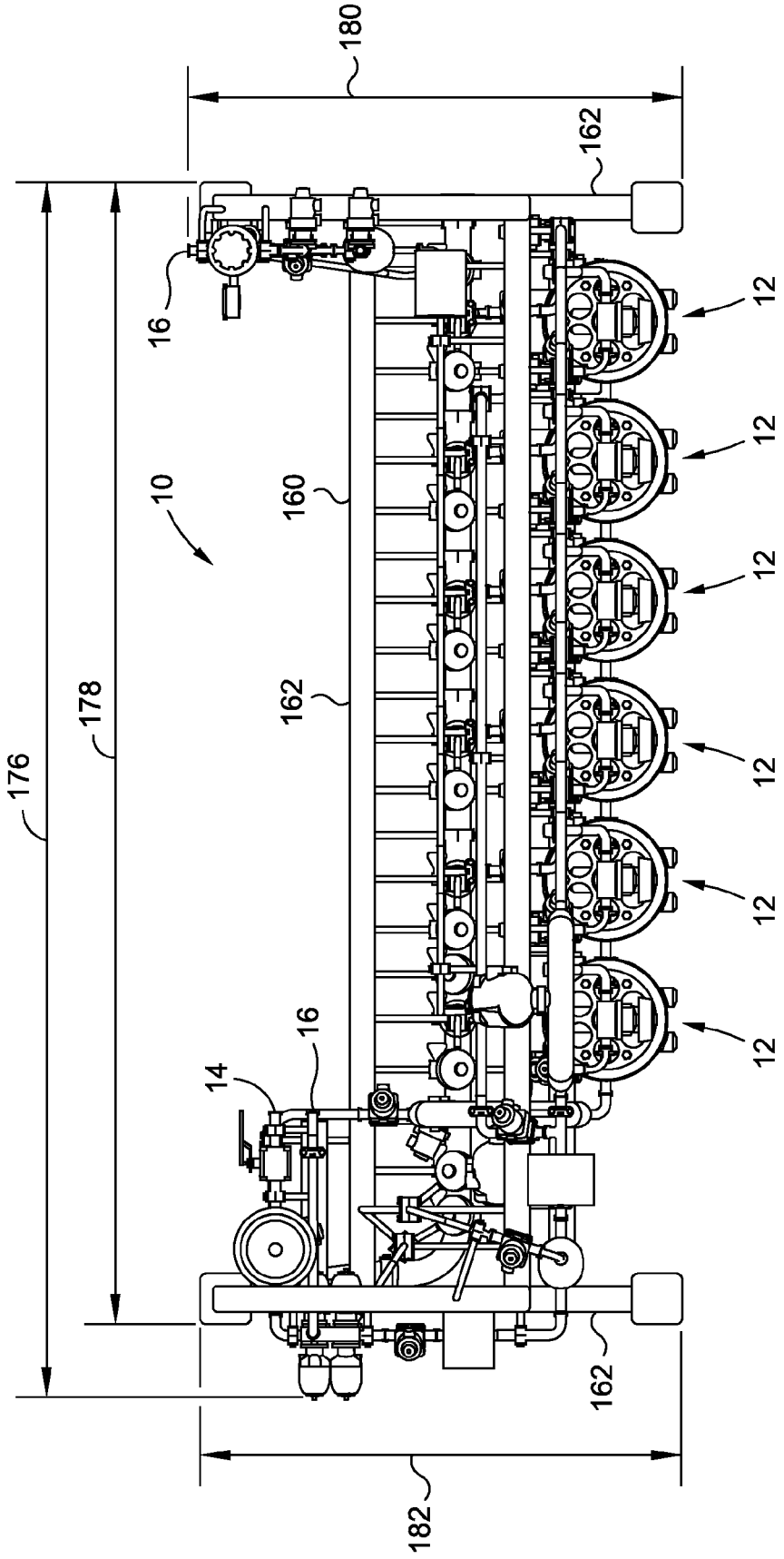

FIG. 6G

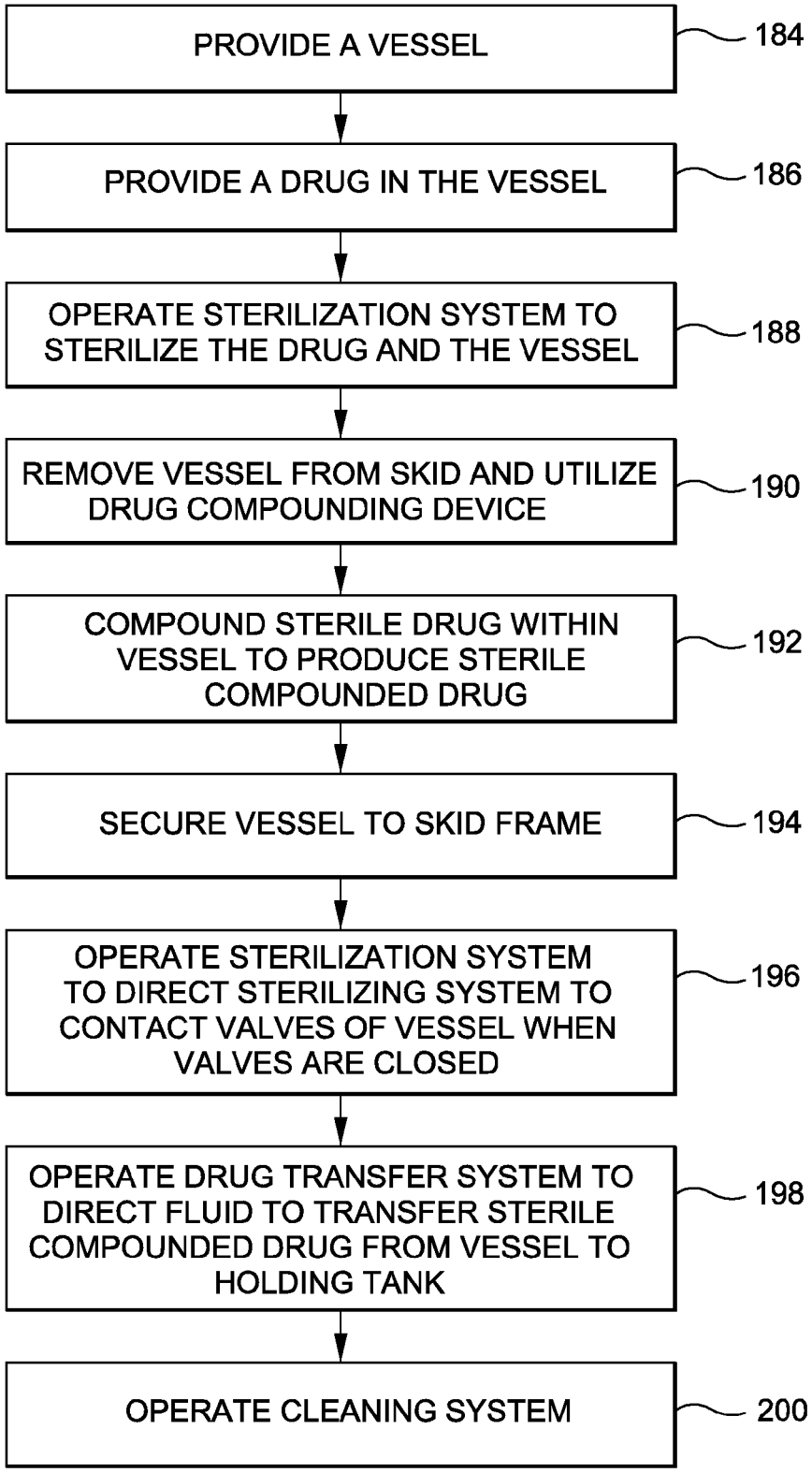
PROVIDE A VESSEL
184
PROVIDE A DRUG IN THE VESSEL
186
OPERATE STERILIZATION SYSTEM TO STERILIZE THE DRUG AND THE VESSEL
188
REMOVE VESSEL FROM SKID AND UTILIZE DRUG COMPOUNDING DEVICE
190
COMPOUND STERILE DRUG WITHIN VESSEL TO PRODUCE STERILE COMPOUNDED DRUG
192
SECURE VESSEL TO SKID FRAME
194
OPERATE STERILIZATION SYSTEM TO DIRECT STERILIZING SYSTEM TO CONTACT VALVES OF VESSEL WHEN VALVES ARE CLOSED
196
OPERATE DRUG TRANSFER SYSTEM TO DIRECT FLUID TO TRANSFER STERILE COMPOUNDED DRUG FROM VESSEL TO HOLDING TANK
198
OPERATE CLEANING SYSTEM
200

FIG. 7A

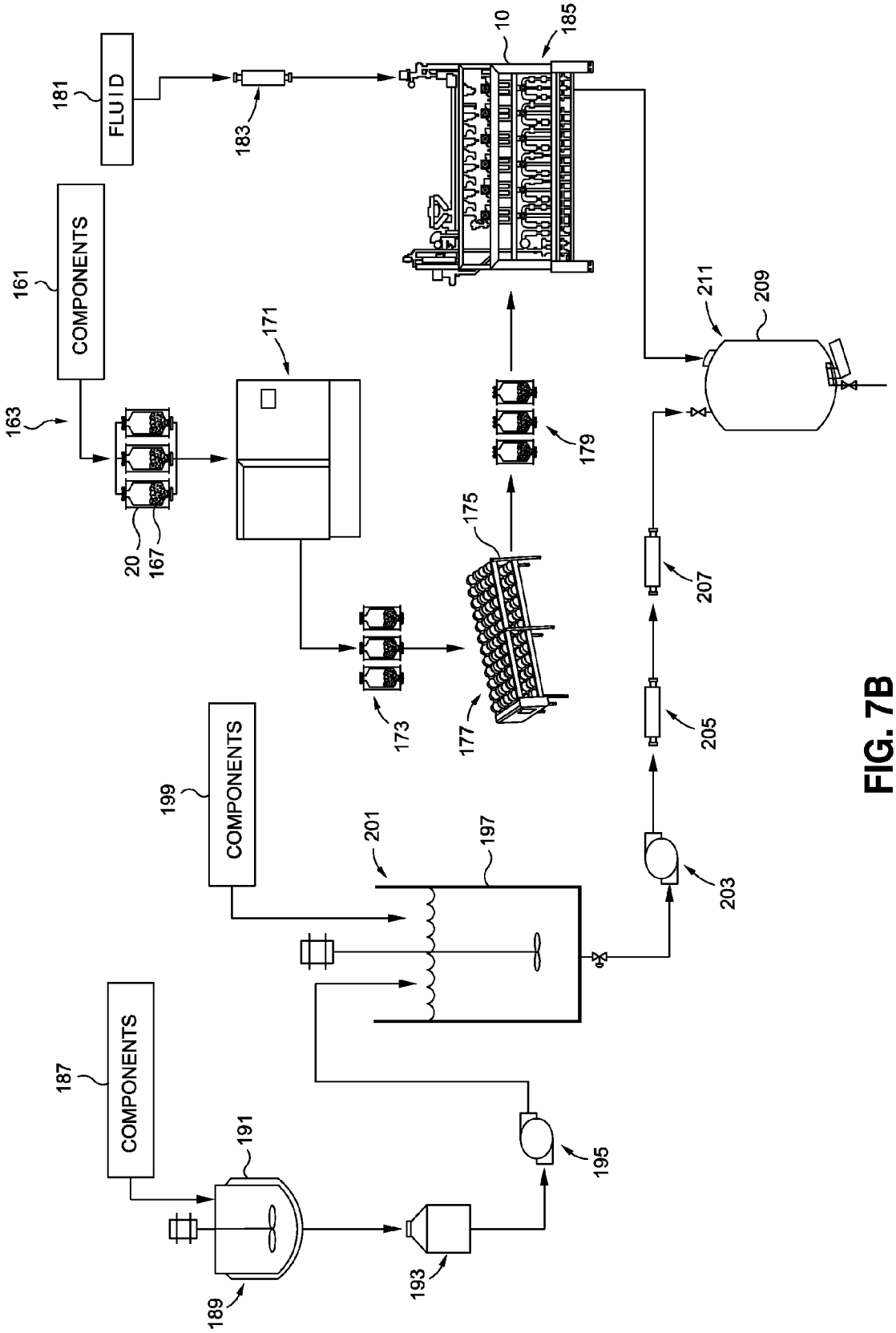
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FIG. 7B

FIG. 8

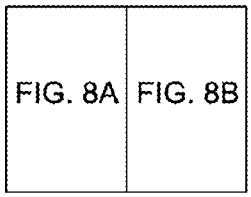
FIG. 8A
FIG. 8B

FIG. 8A

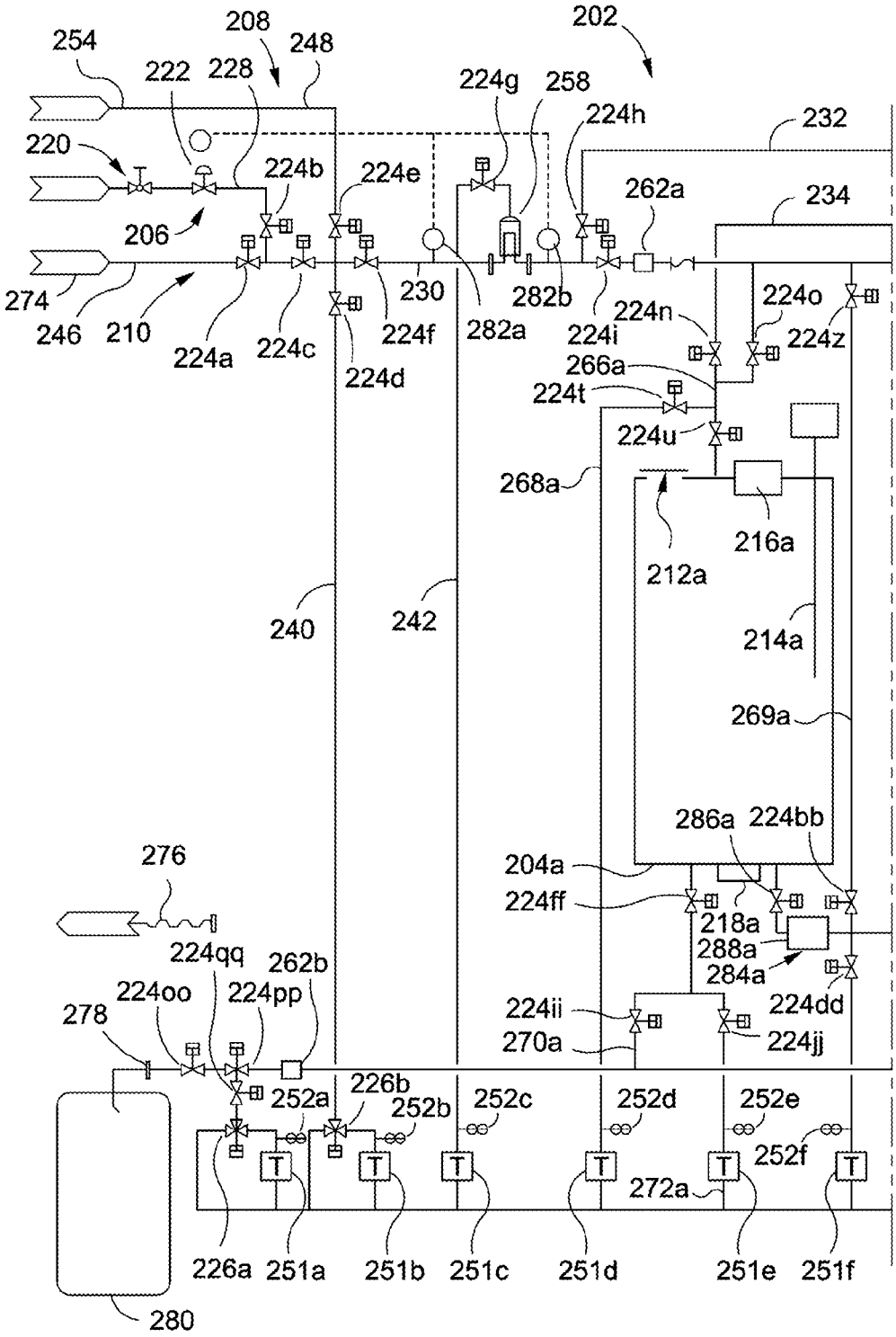
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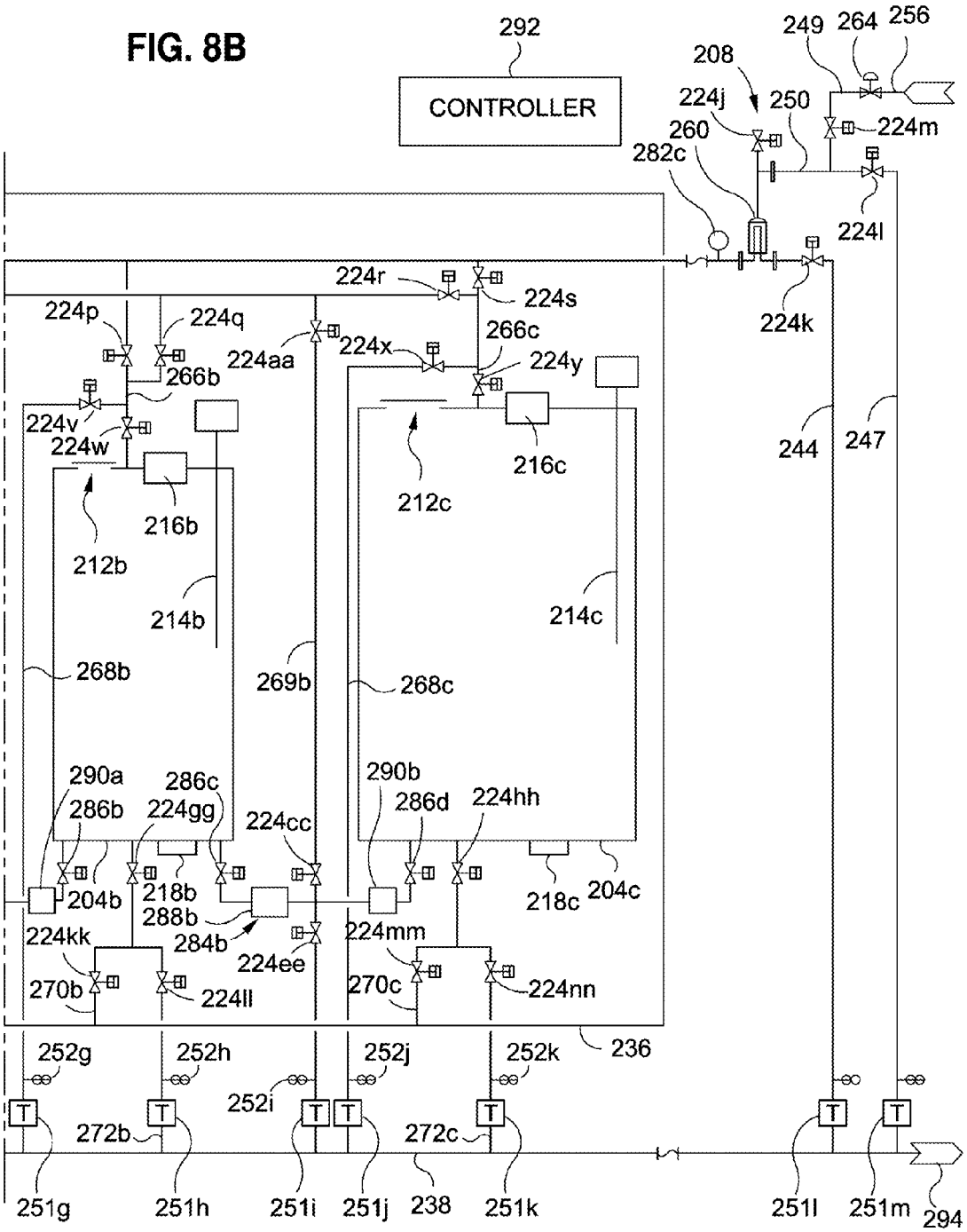
FIG. 8B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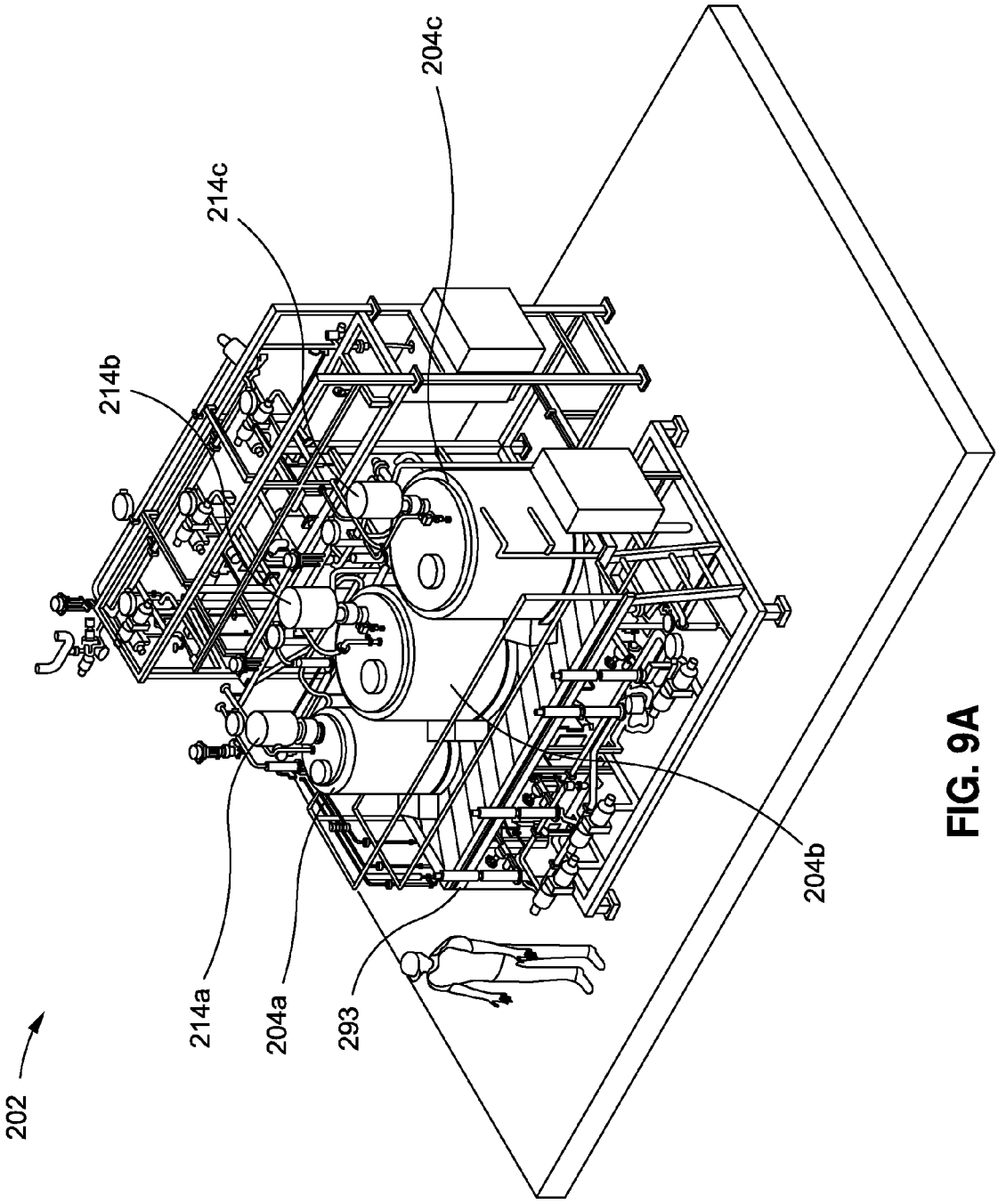
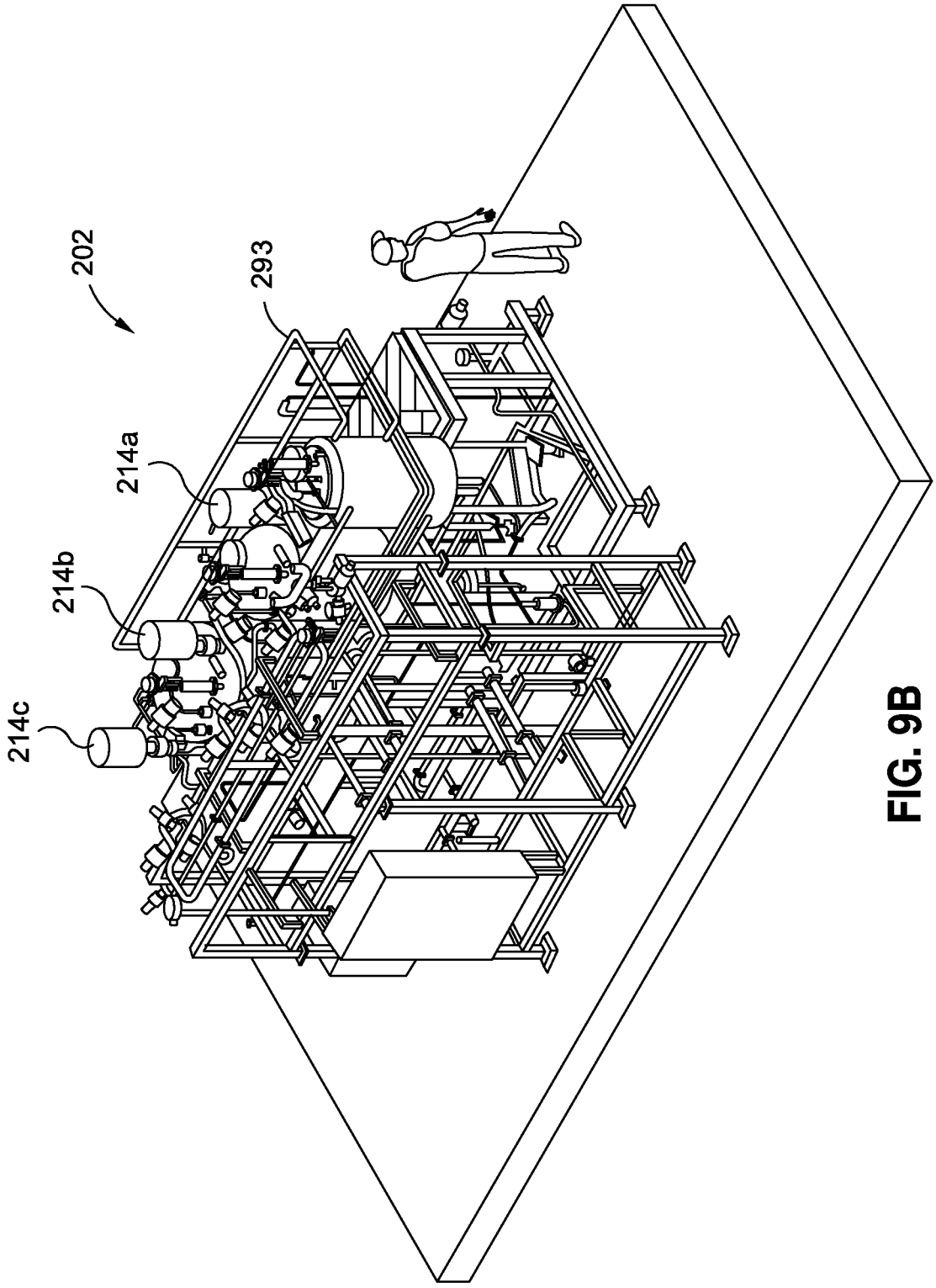


FIG. 9A



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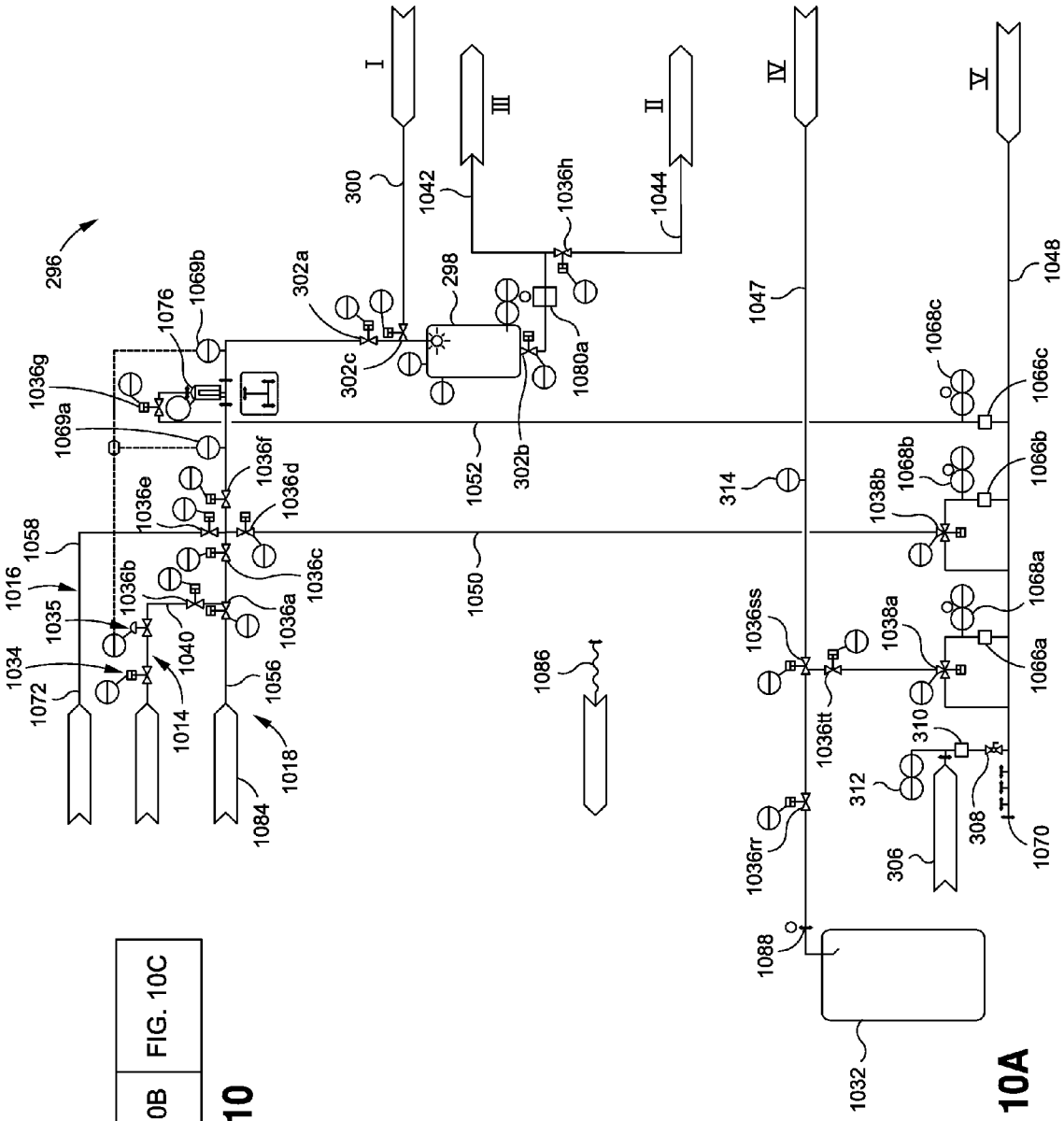

FIG. 10

FIG. 10A	FIG. 10B	FIG. 10C

FIG. 10A

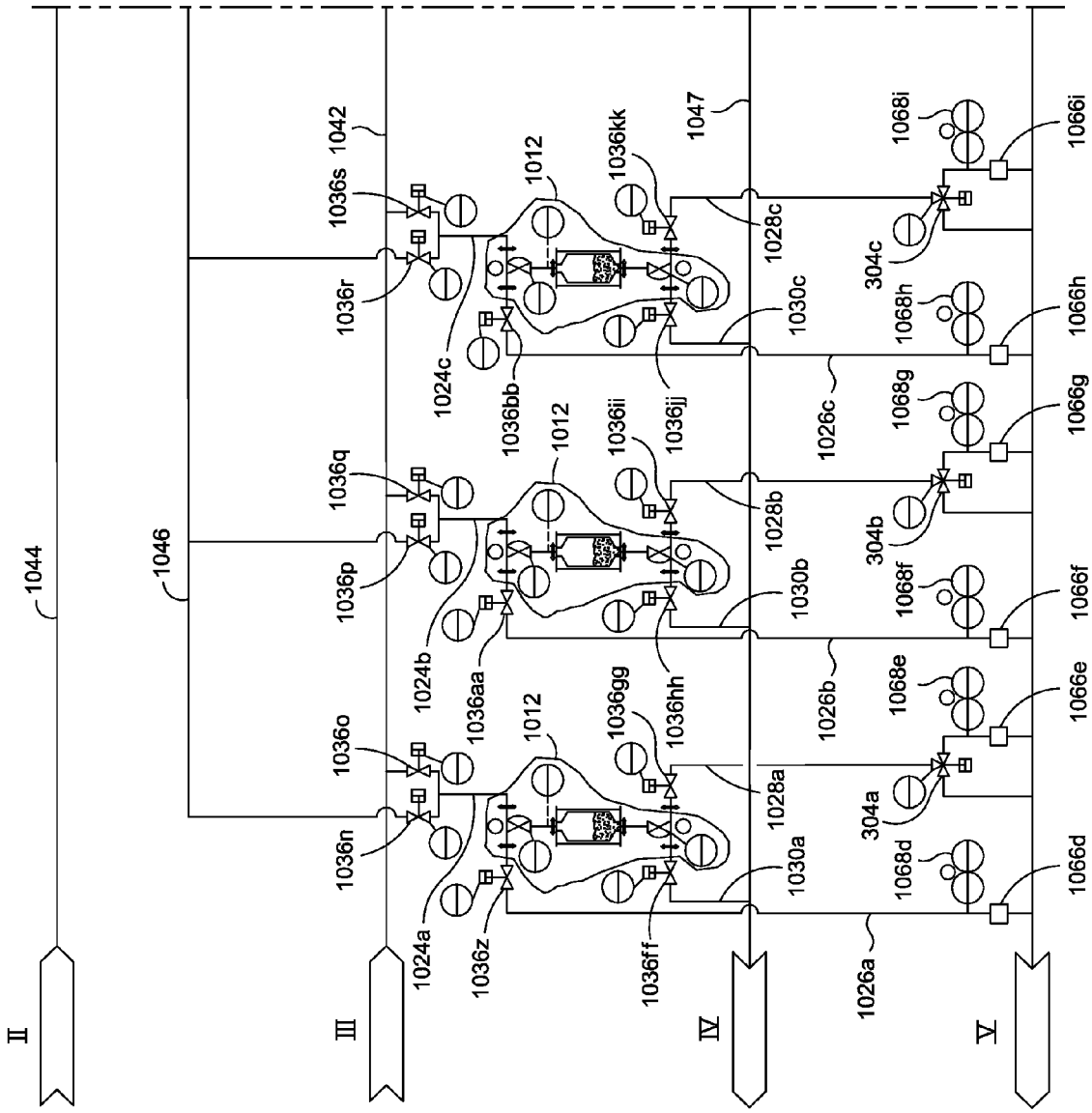
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FIG. 10B

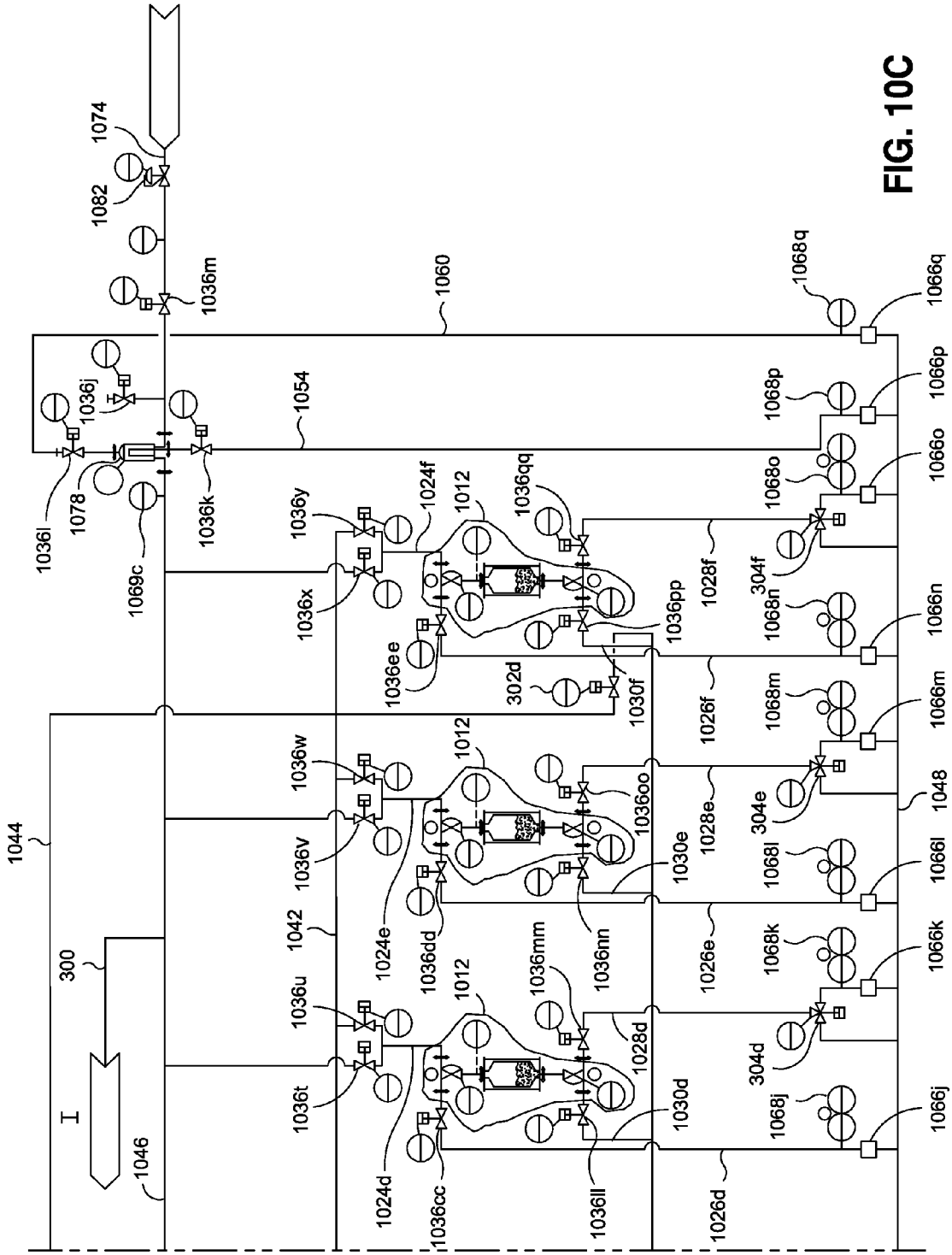
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FIG. 10C

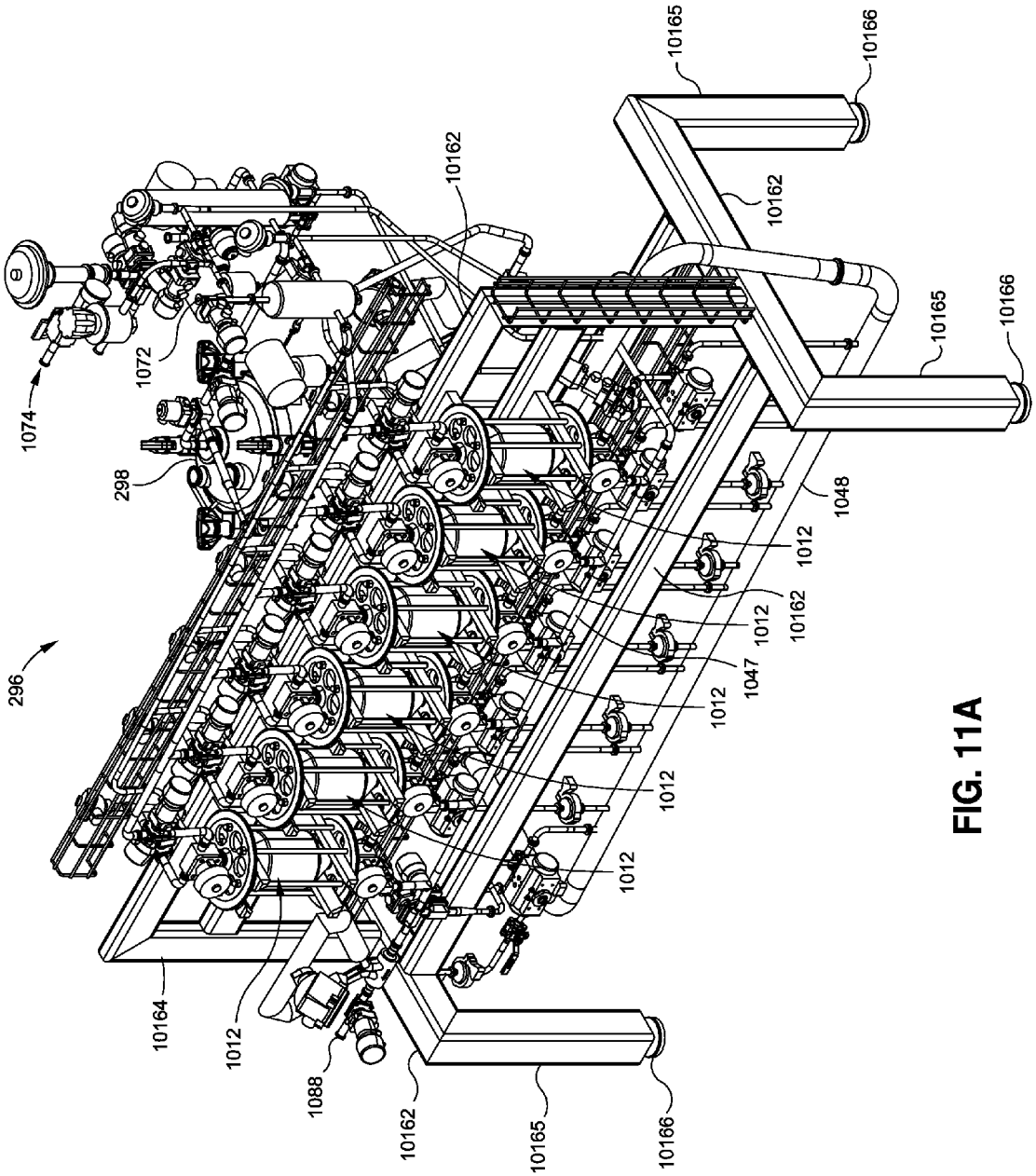
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FIG. 11A

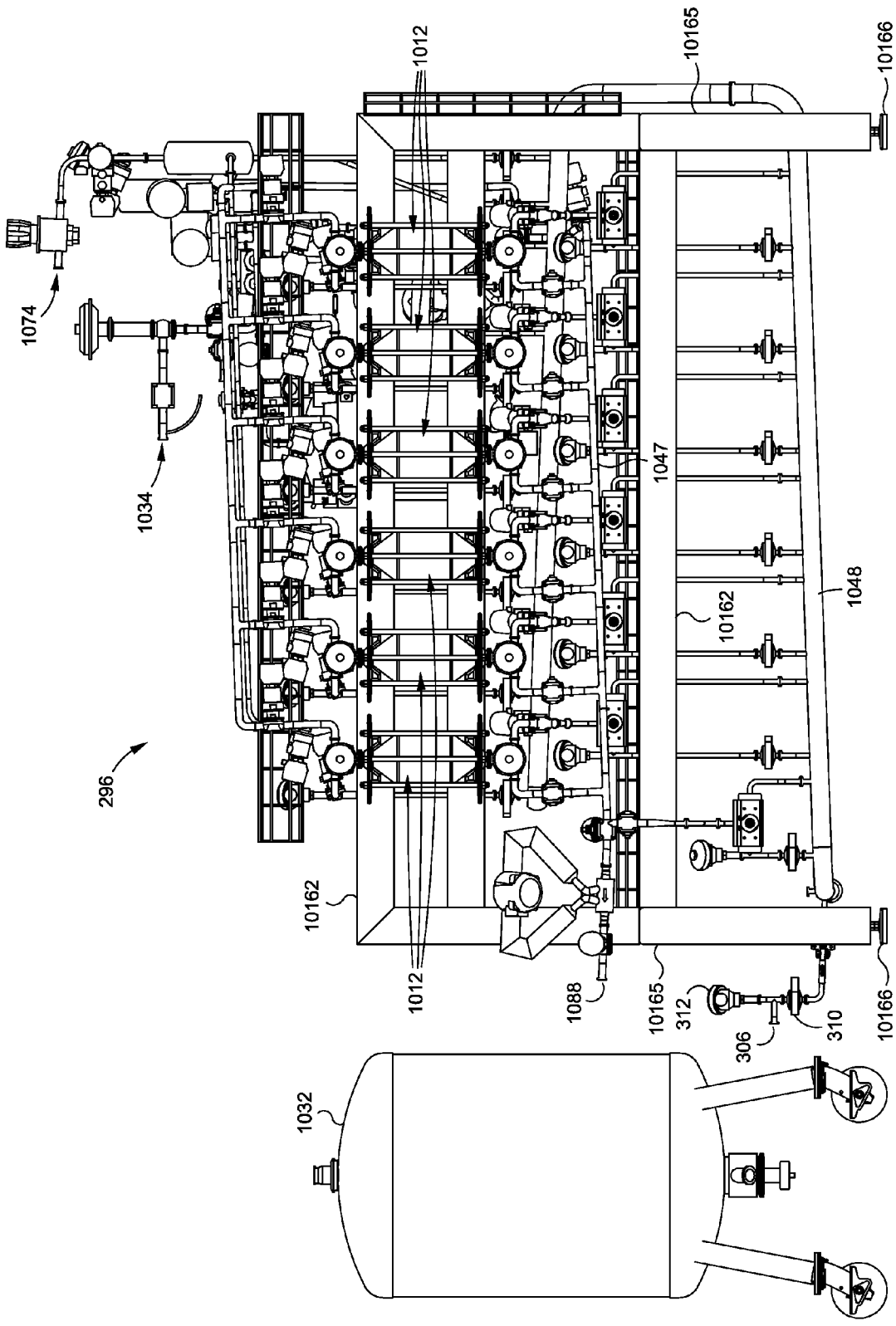
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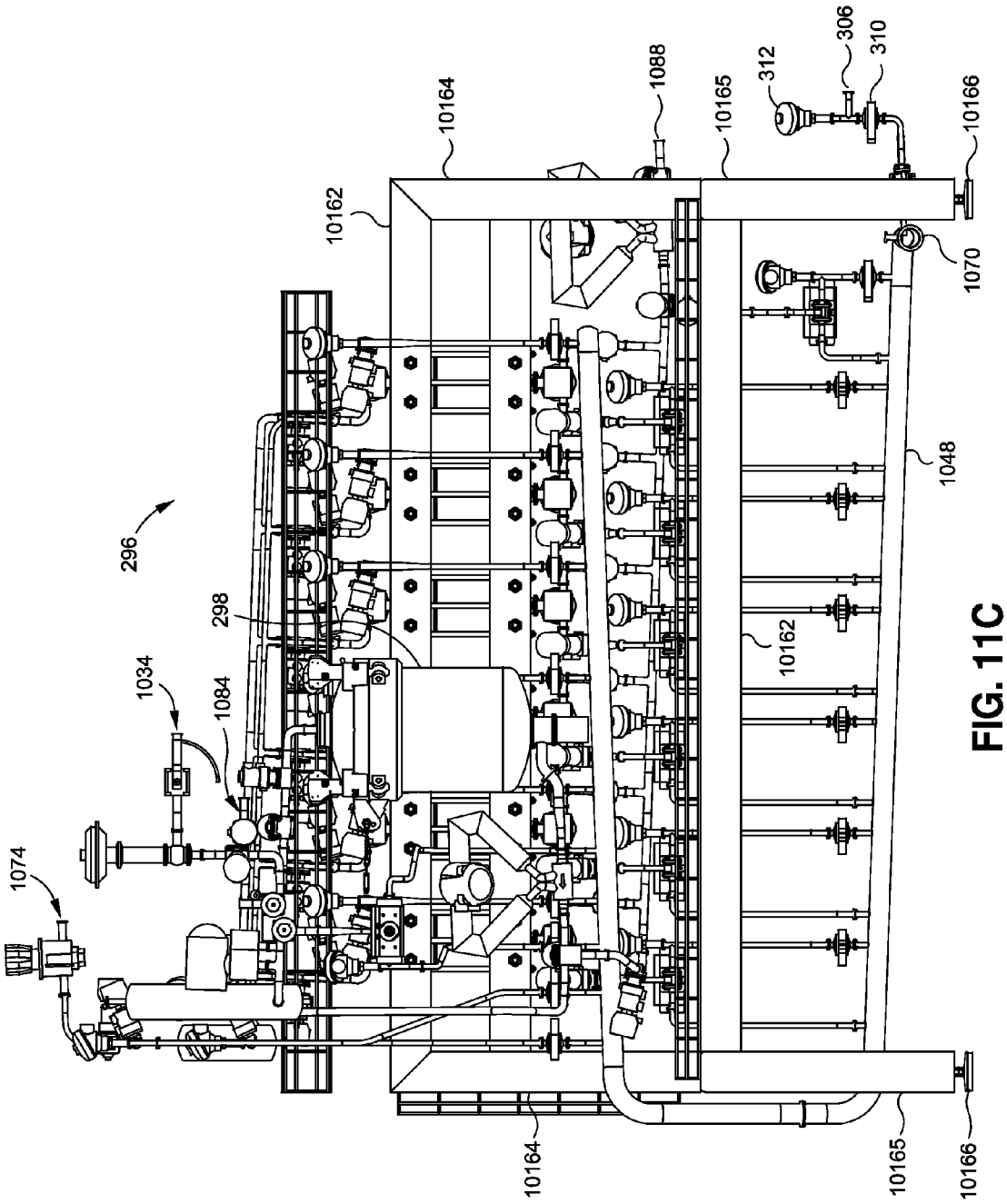
FIG. 11B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10166

FIG. 11C

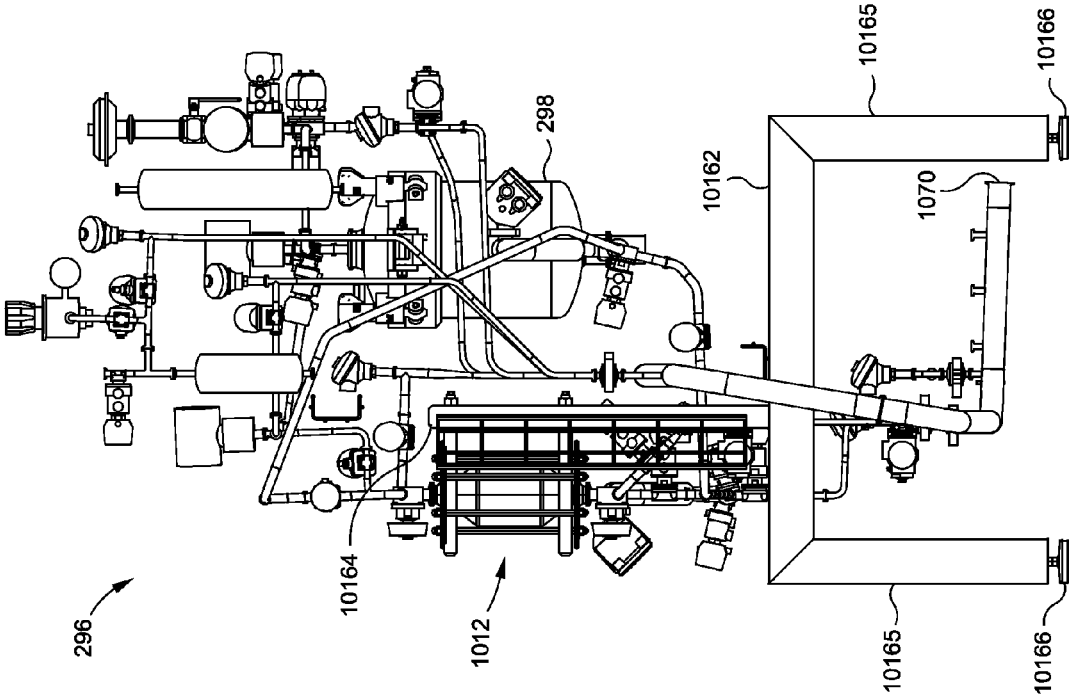

FIG. 11D

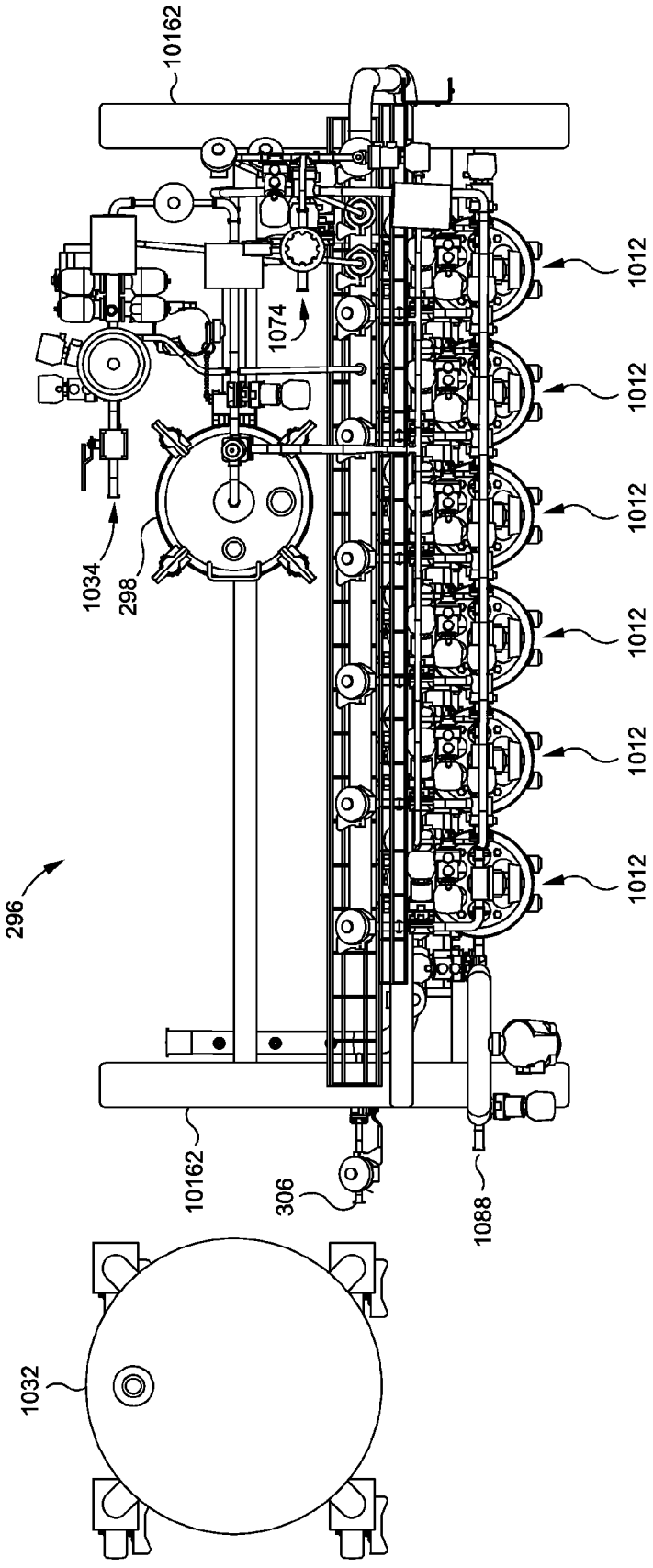
10162
1012
1012
1012
1012
1012
1012
1074
1034
298
296
10162
306
1088
1032

FIG. 11E

DRUG COMPOUNDING SKID AND COMPOUNDING METHOD

CROSS-REFERENCE

This application is a continuation-in-part of U.S. patent application Ser. No. 13/756,461, filed Jan. 31, 2013, the entire contents of which is incorporated here by reference.

FIELD OF THE INVENTION

The present disclosure relates to drug compounding skids and methods.

BACKGROUND OF INVENTION

Methods and apparatuses for producing compounded drugs typically involve aseptic environments which require numerous precautions to assure the drugs produced remain sterile for human use. Often, such methods include an individual compounding a drug upon a mill within a compounding vessel. The individual then physically reaches into the compounding vessel to scoop out the drugs that have been compounded therein. The individual places the received drugs in a storage container for further processing or delivery for packaging.

The individual must be certain to not contaminate the compounded drugs with any aseptic materials, such as bacteria or other undesired microbes.

In addition, the individual must labor to physically remove the drugs, and then clean the compounding vessel as desired.

There is therefore a need to provide for ease of sterile transfer of compounded drugs.

There is also a need for further ease of automation of compounding products.

SUMMARY OF THE INVENTION

Aspects of the present specification disclose a skid apparatus for sterile transfer of a compounded drug.

In one embodiment, the present specification discloses a frame configured to stand upon a supporting surface. A vessel has an interior chamber and an outer surface with a first open end and a second open end, and configured to retain a drug that is compounded within the interior chamber, and having a first valve at the first open end and a second valve at the second open end that are configured to form a sterile seal of the drug compounded within the interior chamber. The vessel is configured to be releasably retained by the frame and to be used with a drug compounding device that compounds the drug within the interior chamber when the vessel is released from the frame.

A sterilization system is coupled to the frame and is configured to direct sterilizing steam to contact and sterilize the first valve and the second valve when the vessel is retained by the frame.

A drug transfer system is coupled to the frame and is configured to direct fluid such that the fluid passes through the first valve, then through the interior chamber, and then through the second valve to transfer the drug that is compounded within the interior chamber to a holding tank when the vessel is retained by the frame.

In one embodiment, the present specification discloses a method for sterile transfer of a sterile compounded drug. The method includes providing a vessel having an interior chamber and an outer surface with a first open end and a second open end, and having a first valve at the first open end and a second valve at the second open end, the vessel retaining the sterile compounded drug in the interior chamber, the first valve and the second valve both being closed and forming a sterile seal of the sterile compounded drug within the interior chamber. The method includes securing the vessel to a skid frame. The method includes operating a sterilization system coupled to the skid frame to direct sterilizing steam to contact and sterilize the first valve and the second valve when the first valve and the second valve are closed. The method includes operating a drug transfer system coupled to the skid frame to direct fluid through the first valve when the first valve is open, then through the interior chamber, and then through the second valve when the second valve is open, to transfer the sterile compounded drug from the interior chamber to a holding tank.

In one embodiment, the present specification discloses a skid apparatus for use to compound drugs. The skid apparatus includes a frame configured to stand upon a supporting surface.

A first drug compounding tank is coupled to the frame and configured to retain a drug for compounding within the first drug compounding tank.

A first agitation device is coupled to the first drug compounding tank and configured to agitate the drug retained within the first drug compounding tank when the drug retained within the first drug compounding tank is being compounded.

A second drug compounding tank is coupled to the frame and is configured to retain a drug for compounding within the second drug compounding tank.

A second agitation device is coupled to the second drug compounding tank and is configured to agitate the drug retained within the second drug compounding tank when the drug retained within the second drug compounding tank is being compounded.

A first conduit is configured to allow the drug retained within the first drug compounding tank to transfer to the second drug compounding tank.

A second conduit is configured to allow the drug retained within the second drug compounding tank to transfer to a holding tank.

BRIEF DESCRIPTION OF THE DRAWINGS

Features and advantages of the present invention will become appreciated as the same become better understood with reference to the specification, claims, and appended drawings wherein:

FIG. **1** is a schematic view of a drug compounding skid according to an embodiment of the present invention, divided into parts FIG. **1**A and FIG. **1**B;

FIG. **2**A is a side exploded view of components of a vessel according to an embodiment of the present invention;

FIG. **2**B is a top view of a filter according to an embodiment of the present invention;

FIG. **2**C is a top view of a filter according to an embodiment of the present invention;

FIG. **3**A is a side view of components of a vessel according to an embodiment of the present invention;

FIG. **3**B is a side cross sectional view of components of a vessel according to an embodiment of the present invention;

FIG. **3**C is a perspective view of components of a vessel according to an embodiment of the present invention;

FIG. **4**A is a side schematic view of components of a vessel according to an embodiment of the present invention;

FIG. **4**B is an end view of components of a vessel according to an embodiment of the present invention;

FIG. **5**A is a perspective view of a valve according to an embodiment of the present invention;

FIG. **5**B is a side view of a valve according to an embodiment of the present invention;

FIG. **5**C is a front view of a valve according to an embodiment of the present invention;

FIG. **5**D is a top view of a valve according to an embodiment of the present invention;

FIG. **6**A is a front perspective view of a drug compounding skid according to an embodiment of the present invention;

FIG. **6**B is a rear perspective view of the drug compounding skid shown in FIG. **6**A according to an embodiment of the present invention;

FIG. **6**C is a front view of the drug compounding skid shown in FIG. **6**A according to an embodiment of the present invention;

FIG. **6**D is a rear view of the drug compounding skid shown in FIG. **6**A according to an embodiment of the present invention;

FIG. **6**E is a left side view of the drug compounding skid shown in FIG. **6**A according to an embodiment of the present invention;

FIG. **6**F is a right side view of the drug compounding skid shown in FIG. **6**A according to an embodiment of the present invention;

FIG. **6**G is a top view of the drug compounding skid shown in FIG. **6**A according to an embodiment of the present invention;

FIG. **7**A is a flow chart of a method of utilizing a drug compounding skid according to an embodiment of the present invention;

FIG. **7**B is a process schematic illustrating a method of utilizing a drug compounding skid according to an embodiment of the present invention;

FIG. **8** is schematic view of a drug compounding skid according to an embodiment of the present invention, divided into parts FIG. **8**A and FIG. **8**B;

FIG. **9**A is a front perspective view of a drug compounding skid according to an embodiment of the present invention;

FIG. **9**B is a rear perspective view of the drug compounding skid shown in FIG. **9**A according to an embodiment of the present invention

FIG. **10** is schematic view of a drug compounding skid according to an embodiment of the present invention, divided into parts FIG. **10**A, FIG. **10**B and FIG. **10**C;

FIG. **11**A is a front perspective view of a drug compounding skid according to an embodiment of the present invention;

FIG. **11**B is a front view of the drug compounding skid shown in FIG. **11**A according to an embodiment of the present invention;

FIG. **11**C is a rear view of the drug compounding skid shown in FIG. **11**A according to an embodiment of the present invention;

FIG. **11**D is a right side view of the drug compounding skid shown in FIG. **11**A according to an embodiment of the present invention; and

FIG. **11**E is a top view of the drug compounding skid shown in FIG. **11**A according to an embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **1** illustrates a schematic view of a drug compounding skid **10** for sterile transfer of a compounded drug. The skid **10** includes a plurality of vessels **12**, a sterilization system **14**, and a drug transfer system **16**. The skid **10** may also include a cleaning system **18** to allow the skid **10** to be cleaned in place.

Each vessel **12** is configured for a drug to be compounded within the vessel **12**. The vessel **12** has an interior chamber for retaining the drug, and two open ends. The two open ends are positioned substantially opposite from each other. Each open end forms an entrance for the vessel **12**, to allow a drug, or combination of drugs to be passed into the interior chamber.

The vessel **12** has sufficient strength to allow a drug to be compounded within the vessel **12**. For example, the vessel **12** has sufficient strength to withstand forces applied to the vessel **12** by a drug compounding device. The drug compounding device may comprise a mill, or other form of agitator that may act upon the vessel **12** to compound a drug contained therein. In addition, the vessel **12** has sufficient strength to contain grinding beads that are configured to grind the drug when it is being compounded.

A first valve **20** is positioned at one of the open ends of the vessel **12**. The first valves **20***a*, **20***b*, **20***c*, **20***d*, **20***e*, **20***f* may be collectively referred to as **20**. Similarly, all other multiple reference numbers disclosed in this application, followed by a subsequent letter, may be collectively referred to by the preceding reference number. A second valve **22** is positioned at the other open end of the vessel **12**. The first valve **20** and second valve **22** seal the interior chamber of the vessel **12** to prevent the drug contained within the vessel **12** from being released. In addition, the first valve **20** and second valve **22** may each be configured to form a sterile seal of the drug contained within the vessel **12**, namely, the first and second valves **20**, **22** may be structured to prevent microbes or microorganisms from easily passing through the valves **20**, **22** and into the interior chamber. The valves **20**, **22** may be configured to maintain the sterility of a drug contained within the vessel **12**.

The vessel **12** is configured to be releasably joined to other components of the skid **10**. The vessel **12** may be releasably coupled to conduits of the skid **10**, including conduits **24**, **26**, **28**, **30** of the sterilization system **14**. The vessel **12** may be releasably coupled by the valves **20**, **22** being joined to the conduits **24**, **26**, **28**, **30** and also being capable of being released from the conduits **24**, **26**, **28**, **30** to allow the entire vessel **12** to be released from the remaining portions of the skid **10**.

The vessel **12** releasably joins with the other components of the skid **10** to allow the vessel **12** to be removed from the skid **10** and placed upon a separate drug compounding device, such as a mill. In this configuration, the drug compounding process takes place on a separate device. The vessel **12** with the compounded drug may be subsequently joined to conduits of the skid **10** to allow the compounded drug to be transferred out of the vessel **12** and to a holding tank **32**.

The sterilization system **14** includes a sterilizing steam input **34**, valves **35**, **36**, **38**, and conduits **24**, **26**, **28**, **30**, **40**, **42**, **44**, **46**, **47**, **48**, **50**, **52**, **54**, **56**, **58**, **60**, **62**, **64**. The sterilization system may also include steam traps **66**, thermal sensors **68** and pressure sensors **69**.

The steam input **34** is configured to receive sterilizing steam from an outside source, for example, from a steam generator device. The steam generator device may include a heater, vaporizer, or the like. The steam input **34** may include a ball valve that is capable of being opened and closed to selectively allow steam to enter the conduit **40** from the outside source. A steam control valve **35** may also be used to control the rate at which steam enters the conduit **40**.

The conduits **24**, **26**, **28**, **30**, **40**, **42**, **44**, **46**, **47**, **48**, **50**, **52**, **54**, **56**, **58**, **60**, **62**, **64** may comprise pipes. The pipes may

have sufficient strength to withstand the pressure of sterilizing steam being passed therethrough. The pipes may be constructed in a manner that they may be sterilized.

The valves **35**, **36**, **38** are configured to open or close to block the passage of steam or to allow steam to pass therethrough. In one embodiment, the valve **35** may comprise a sanitary control valve. The valves **36** may comprise a two-way directional valve. The valves **38** may each comprise a three-way directional valve. In one embodiment, the valves **36**, **38** may each comprise a diaphragm valve. In one embodiment, the valves **36**, **38** may each comprise a pneumatically actuated valve. In one embodiment, the valves **36**, **38** may each comprise an electronically activated valve. In one embodiment, the valves **36**, **38** may each comprise any combination of a diaphragm, pneumatically actuated, or electronically activated valve, as desired.

The thermal sensors **68** of the sterilization system **14** may be capable of detecting a temperature of the sterilizing steam used in the sterilization system **14**. The thermal sensors **68** may be used to indicate when the temperature of the steam is too high or too low to effectively sterilize components of the skid **10**, and may provide an indication to either increase a temperature of the steam input into the steam input **34**, or to change a rate at which steam enters the steam input **34** or passes through the steam control valve **35**.

The pressure sensors **69** of the sterilization system **14** may be capable of detecting a pressure of the sterilizing steam used in the sterilization system **14**. The pressure sensors **69** may be used to indicate when a pressure of the steam is too high or too low to effectively sterilize components of the skid **10**, and may provide an indication to either increase a pressure of the steam input into the steam input **34**, or to change a rate at which steam enters the steam input **34** or passes through the steam control valve **35**.

The sterilization system **14** is configured to pipe sterilizing steam throughout the conduits **24**, **26**, **28**, **30**, **40**, **42**, **44**, **46**, **47**, **48**, **50**, **52**, **54**, **56**, **58**, **60**, **62**, **64** and through the valves **35**, **36**, **38** to sterilize the conduits **24**, **26**, **28**, **30**, **40**, **42**, **44**, **46**, **47**, **48**, **50**, **52**, **54**, **56**, **58**, **60**, **62**, **64** and valves **35**, **36**, **38**, and any other desired feature of the skid **10**.

The sterilization system **14** may also be configured to sterilize the valves **20**, **22** of each of the vessels **12**. The sterilization system **14** may sterilize the valves **20**, **22** if the valves **20**, **22** are opened or closed. To sterilize the valves **20**, **22** of each of the vessels **12** when the valves **20**, **22** are closed, steam may be piped through the steam input **34**, through the conduit **40**, then through the conduit **42** until it passes through the conduit **24**. The steam may then contact an outer surface of the valve **20** to sterilize the outer surface of the valve **20**. In addition, the steam may be directed through the steam input **34**, through the conduit **40**, through the conduit **42**, through the conduit **44**, through the conduit **47** until it passes through the conduit **30**. The steam may then contact an outer surface of the valve **22** to sterilize the outer surface of the valve **22**.

The sterilization system **14** may also be configured to sterilize the interior chamber of each of the vessels **12** and an interior surface of the valves **20**, **22** when either of the valves **20**, **22** are open. To sterilize these parts of the skid **10**, the steam may be piped through the conduit **40**, through the conduit **42**, through the conduit **24**, through the valve **20**, through the interior chamber of the vessel, and then through the valve **22**. The steam may also pass through the conduit **26**, and through conduit **28** and conduit **30** to sterilize these parts of the skid **10**.

Upon sterilizing steam passing through the conduits **24**, **26**, **28**, **30**, **40**, **42**, **44**, **46**, **47**, **50**, **52**, **54**, **56**, **58**, **60**, **62**, **64** and through valves **35**, **36**, **38** of the skid, the steam may reach the steam traps **66**. The steam traps **66** lock the sterilizing steam within the conduits **24**, **26**, **28**, **30**, **40**, **42**, **44**, **46**, **47**, **50**, **52**, **54**, **56**, **58**, **60**, **62**, **64** of the skid **10**. Condensation produced from the sterilizing steam is collected within the steam traps **66** and is passed to the conduit **48**. The conduit **48** conveys the condensation to a drain **70** for removal from the sterilization system **14**.

The drug transfer system **16** includes a fluid inlet, or fluid inlets, which may include a water inlet **72**, and an air inlet **74**. The drug transfer system **16** also includes conduits **58**, **42**, **24**, **30**, **46**, **47**, **62**, **64** and valves **36***c*, **36***d*, **36***e*, **36***f*, **36***g*, **36***h*, **36***i*, **36***j*, **36***k*, **36***l*, **36***m*, **36***n*, **36***o*, **36***p*, **36***q*, **36***r*, **36***s*, **36***t*, **36***u*, **36***v*, **36***w*, **36***x*, **36***y*, **36***ff*, **36***gg*, **36***hh*, **36***ii*, **36***jj*, **36***kk*, **36***ll*, **36***mm*, **36***nn*, **36***oo*, **36***pp*, **36***qq*, **36***rr*, **36***ss*, **36***tt*, and may include filters **76**, **78**, flow meters **80**, a regulator **82**, and pressure sensors **69**.

The fluid inlets are configured to allow a fluid such as air or water to enter the inlet from an outside source. For example, the water inlet **72** is configured to receive water, preferably purified water, from an outside water source. The water inlet **72** allows the water to enter the conduit **58**. The air inlet **74** is configured to receive air, preferably oil free air, from an outside air source. The outside air source preferably provides pressurized air, and may comprise an air compressor. The air inlet **74** allows the air to enter the conduit **62**.

The water inlet **72** and air inlet **74** may operate in combination to transfer compounded drugs from the vessels **12** to the holding tank **32**. The water inlet **72** may allow water to pass through the conduit **58**, through the valves **36***e*, **36***f*, and through liquid filter **76**. The water then passes through valve **36***i* and valves **36***o*, **36***q*, **36***s*, **36***u*, **36***w*, **36***y* to pass into conduit **24**. If the valve **20** is open, then the water may enter the interior chamber of the vessel **12**. If the valve **22** and valve **36***ff*, **36***hh*, **36***jj*, **36***ll*, **36***nn*, **36***pp*, are also open, then the water may flush out the drug compounded within the interior chamber. The water flushes the drug out to conduit **47**, which passes through valves **36***ss*, **36***rr* to holding tank **32**. The flow meters **80***a*, **80***b* may measure the flow of water through conduits **42**, **47** respectively. The valves **36***c*, **36***d*, **36***g*, **36***j*, **36***k*, **36***l*, **36***gg*, **36***ii*, **36***kk*, **36***mm*, **36***oo*, **36***qq*, **36***tt*, **36***z*, **36***aa*, **36***bb*, **36***cc*, **36***dd*, **36***ee* are preferably closed during this operation.

The air inlet **74** is used to drive the fluid through the vessels **12** to allow it to enter the holding tank **32**. The air inlet **74** may allow air to pass through the conduit **62** and through the valve **36***m* so that it passes through conduit **64** and conduit **46**, and passes through valves **36***n*, **36***p*, **36***r*, **36***t*, **36***v*, **36***x*. The air drives the water through the conduit **24**, and conveys it through the valve **20**, through the interior chamber of the vessel **12**, and through the valves **36***ff*, **36***hh*, **36***jj*, **36***ll*, **36***nn*, **36***pp*. The air conveys the water, and the drug through the conduit **47**, through the valves **36***ss*, **36***rr* and to the holding tank **32**. The valves **36***c*, **36***d*, **36***g*, **36***k*, **36***l*, **36***j*, **36***gg*, **36***ii*, **36***kk*, **36***mm*, **36***oo*, **36***qq*, **36***tt*, **36***z*, **36***aa*, **36***bb*, **36***cc*, **36***dd*, **36***ee* are preferably closed during this operation. The air passes through a filter **78** that scrubs particulate matter and microbes from the air. The regulator **82** may be used to control the air pressure passing through the conduits **62**, **64**, **46**, **24**, **30**, **47**. The pressure sensors **69** may be used to provide a measure of the fluid pressure passing through the conduits, to determine if the pressure should be lowered or raised as desired.

The cleaning system **18** includes a cleaning fluid inlet **84** that allows a cleaning fluid to enter the conduit **56**. The cleaning fluid may comprise water, air, or a caustic fluid such as acid or the like. The cleaning fluid may be provided by a remote cleaning device, such as a cleaning skid. The cleaning

fluid may pass through any of the valves **35**, **36**, **38**, and conduits **24**, **26**, **28**, **30**, **40**, **42**, **44**, **46**, **47**, **48**, **50**, **52**, **54**, **56**, **58**, **60**, **62**, **64**. The cleaning fluid may also pass through the steam traps **66**, filters **76**, **78**, flow meters **80**, and regulator **82**. A cleaning system return **86** may be coupled to a coupler **88** that is used to couple the holding tank **32** to the conduit **47**. The cleaning system return **86** retrieves the cleaning fluid from the skid device **10** after the cleaning fluid has passed through the desired components of the skid device **10**. The cleaning fluid preferably does not pass through any portion of the vessels **12**. The vessels **12** are preferably cleaned while the vessels **12** are separate from the remaining portions of the skid device **10**. Any of the inlets **34**, **72**, **74** or valves **35**, **36**, **38** may be closed or opened as desired during the cleaning operation to direct cleaning fluid to the desired portions of the skid device **10** to be cleaned.

In one embodiment, a controller device **90** may be configured to control inlets **72**, **34**, **84**, **74** and/or valves **20**, **22**, **35**, **36**, **38** and/or regulator **82**. In addition, the controller device **90** may be configured to receive a temperature reading from temperature sensors **68** and/or a pressure reading from pressure sensors **69**. The controller device **90** may also be configured to receive a rate of flow reading from flow sensors **80**. The controller device **90** may be configured to electrically and automatically open or close one or more of inlets **72**, **34**, **84**, **74** and/or valves **20**, **22**, **35**, **36**, **38** and/or regulator **82** to operate any of the sterilization system **14**, the drug transfer system **16**, or the cleaning system **18**. The controller device **90** may comprise an electrical controller device including a processor and memory, and capable of being programmed for operation. In one embodiment, the controller device **90** may comprise a dedicated controller designed to only perform certain tasks related to the sterilization system **14**, the drug transfer system **16**, or the cleaning system **18**. The controller device **90** may be electrically wired to any component of the skid device **10** to provide for desired operation.

In a mode of operation in which the controller device **90** operates the sterilization system **14**, the controller device **90** may open or close any of the valves **35**, **36**, **38** to allow sterilizing steam to sterilize any desired component of the skid device **10**. The controller device **90** may receive a temperature reading from one of the temperature sensors **68** to determine if the temperature of the sterilizing steam is too high or too low, and may open or close one or more valves **35**, **36**, **38** to allow the temperature to reach a desired point. The controller device may also receive a pressure reading from one of the pressure sensors **69** to determine if the pressure of the sterilizing steam is too high or too low, and may open or close one or more valves **35**, **36**, **38** to allow the pressure to reach a desired point. In addition, the controller device **90** may operate to vary the temperature or pressure of the sterilizing steam by controlling the remote steam generation device. In one embodiment, the controller device **90** may send a signal for a user to vary the temperature or pressure of the sterilizing steam by controlling the remote steam generation device. In one embodiment, the controller device **90** may send a signal for a user to vary the temperature or pressure of the sterilizing steam by controlling the amount of steam passing through the steam inlet **34** and the steam control valve **35**. The signal may comprise an alarm or the like.

In one embodiment, the controller device **90** may be configured to open or close one or more of valves **20**, **22** to allow sterilizing steam to contact a desired portion of the vessels **12**.

In a mode of operation in which the controller device **90** operates the drug transfer system **16**, the controller device **90** may open or close any of the valves **36** and operate regulator **82** to allow fluid to convey a compounded drug contained within the vessel **12** to the holding tank **32**. The controller device **90** may receive a flow reading from one of the flow sensors **80** to determine if the rate of flow of the fluid, including water and/or air is too high or too low, and may open or close one or more valves **36** or regulator **82** to allow the flow rate to reach a desired point. The controller device may also receive a pressure reading from one of the pressure sensors **69** to determine if the pressure of the fluid is too high or too low, and may open or close one or more valves **36** or regulator **82** to allow the fluid pressure to reach a desired point. In addition, the controller device **90** may operate to vary the flow rate and/or pressure of the fluid by controlling the remote water supply device and/or the air pressure device. In one embodiment, the controller device **90** may send a signal for a user to vary the flow and/or pressure of the fluid by controlling the water supply device and/or the air pressure device. In one embodiment, the controller device **90** may send a signal for a user to vary the flow rate and/or pressure of the air by controlling the amount of air passing through the air inlet **74** and the regulator **82**. The signal may comprise an alarm or the like.

In one embodiment, the controller device **90** may be configured to open or close one or more of valves **20**, **22** to allow fluid to convey a compounded drug contained within the vessel **12** to the holding tank **32**

In a mode of operation in which the controller device **90** operates the cleaning system **18**, the controller device **90** may open any of the valves **35**, **36**, **38** to allow a cleaning fluid to clean any desired component of the skid device **10**. The controller device **90** may receive a flow reading from one of the flow sensors **80** to determine the rate of flow of the cleaning fluid, and may open or close one or more valves **35**, **36**, **38** to allow the flow rate to reach a desired point. In addition, the controller device **90** may operate to vary the flow rate of the cleaning fluid by controlling the remote cleaning device. In one embodiment, the controller device **90** may send a signal for a user to vary the flow of the cleaning fluid by controlling the remote cleaning device. The signal may comprise an alarm or the like.

FIG. **2**A illustrates a side view of a vessel **12** for use with the drug compounding skid **10**. The vessel **12** includes a vessel container **92** with a frame or vessel support **94** positioned around the container **92**. The container **92** includes an interior chamber **95** with a first open end **96** and a second open end **98**. The first valve **20** of the vessel **12** is positioned at the first open end **96** of the interior chamber **95**. The second valve **22** of the vessel **12** is positioned at the second open end **98** of the interior chamber **95**. A first filter **100** is positioned between the first valve **20** and the first open end **96** of the interior chamber **95**. A second filter **102** is positioned between the second valve **22** and the second open end **98** of the interior chamber **95**.

The vessel container **92** has a substantially cylindrically shaped middle portion **104** and two dome shaped end portions **106**, **108**. The middle portion **104** and end portions **106**, **108** surround the interior chamber **95**. The open ends **96**, **98** are positioned at the dome shaped end portions **106**, **108** and open into the interior chamber **95**. The vessel container **92** is preferably made of glass, with strength sufficient to withstand a drug being compounded within the interior chamber **95**. In other embodiments, the vessel container **92** may be made of any other material capable of allowing a drug to be compounded within the interior chamber **95**.

The vessel support **94** includes a top plate **110**, a bottom plate **112** and a plurality of supports **114** joining the top plate **110** to the bottom plate **112**. The top and bottom plates **110**, **112** are structured as substantially flat rigid disks. The top and

bottom plates **110**, **112** may include respective outer rims **116**, **118** that are shaped substantially circular. The substantially circular shape of the outer rims **116**, **118** allows the vessels **12** to be placed upon a mill and to rotate upon the mill if desired. The plates **110**, **112** may include central openings that form the respective open ends **96**, **98** of the interior chamber **95**. The supports **114** comprise rod structures having one end joined to the top plate **110** and another end joined to the bottom plate **112**. The supports **114** provide structural rigidity to the plates **110**, **112** and serve to reduce the amount that the plates **110**, **112** twist relative to the vessel container **92**. The supports **114** reduce the amount that the plates **110**, **112** twist relative to the vessel container **92** if the vessel **12** is rotating upon the mill.

The first valve **20** and second valve **22** are preferably mechanically joined to the respective open ends **96**, **98** of the interior chamber **95** such that the valves **20**, **22** are fixed to the container **92** when the vessel **12** is released from the conduits of the skid **10** as described in relation to FIG. **1**. However, the valves **20**, **22** may also be removable from the open ends **96**, **98** to allow grinding beads or drugs to be inserted or removed from the interior chamber **95**. The valves **20**, **22** are preferably structured to produce a sterile seal of the interior chamber **95**, and may comprise diaphragm valves or the like. In other embodiments, any other type of valve capable of forming a sterile seal of the interior chamber **95** may be used.

The filters **100**, **102** are designed to prevent grinding beads that may be positioned within the interior chamber **95** from exiting the interior chamber **95**. The filters **100**, **102** preferably comprise mesh with apertures sized to allow the drug compounded within the interior chamber **95** to exit from the interior chamber **95**, yet to not allow grinding beads to exit. The filters **100**, **102** may be designed to be removable to allow grinding beads or drugs to be inserted or removed from the interior chamber **95**. The filters **100**, **102** may be removed when the valves **20**, **22** are removed from the open ends **96**, **98** of the interior chamber **95**.

FIG. **2**B illustrates a top view of the filter **100**. FIG. **2**C illustrates a top view of the filter **102**.

FIG. **3**A illustrates a side close up view of the vessel container **92** and the vessel support **94**. FIG. **3**A illustrates the total length **119** of the vessel container **92** and vessel support **94**, which may preferably have a size of approximately 354 millimeters. The total width **120** of the vessel container **92** and vessel support **94** may preferably have a size of approximately 240 millimeters. The width **122** distance between the supports **114** may preferably have a size of approximately 180 millimeters. The thickness **124** of one of the plates **110**, **112** may preferably have a size of approximately 6 millimeters.

FIG. **3**B illustrates a cross sectional close up side view of the vessel container **92** and the vessel support **94**. FIG. **3**B illustrates the interior chamber **95** is a hollow cavity surrounded by the walls of the substantially cylindrically shaped middle portion **104** and two dome shaped end portions **106**, **108**. The open ends **126**, **128** of the vessel container **92** are joined with the plates **110**, **112**, and preferably form a sterile seal with the plates **110**, **112**. The open ends **126**, **128** of the vessel container **92** lead into the open ends **96**, **98** of the interior chamber **95**.

FIG. **3**B illustrates the length **130** between the exterior flat surfaces of the plates **110**, **112**, which may preferably have a size of approximately 313 millimeters. The length **132** between the interior flat surfaces of the plates **110**, **112** may preferably have a size of approximately 293 millimeters. The outer width **133** of one of the open ends **96**, **98** of the interior chamber **95** may preferably have a size of approximately 50 millimeters. The interior width **135** of one of the open ends **96**, **98** of the interior chamber **95** may preferably have a size of approximately 35 millimeters.

FIG. **3**C illustrates a close up perspective view of the vessel container **92** and the vessel support **94**. FIG. **3**C illustrates a plurality of apertures **134** extend through the top plate **110** and the bottom plate **112**. The apertures **134** are sized to reduce the weight of the vessel support **94**, to allow the vessel container **92** and vessel support **94** to be more easily transported, and to improve rotation of the vessel support **94** on a mill if desired.

FIG. **4**A illustrates a side schematic view of the vessel container **92** with the vessel support **94** (shown in FIG. **2**A) removed. The length **136** of the middle portion **104** may preferably have a size of approximately 146 millimeters. The length **138** of the entire vessel container **92** may preferably have a size of approximately 312 millimeters. The length **140** from the end of the end portions **106**, **108** to the end of the open ends **126**, **128** of the vessel container **92** may preferably have a size of approximately 13 millimeters. The dome shaped end portions **106**, **108** angle from the middle portion **104** preferably at an angle **142** of approximately forty five degrees.

FIG. **4**B illustrates an end schematic view of the vessel container **92**. The open end **128** of the vessel container **92** may preferably have an outer diameter **144** of approximately 41 millimeters, and an inner diameter **146** of approximately 34 millimeters. The wall of the open end **128** of the vessel container **92** may preferably have a diameter **148** of approximately 2.5 millimeters. The wall of the middle portion **104** of the vessel container **92** may preferably have a diameter **150** of approximately 5 millimeters. The vessel container **92** may preferably have an outer diameter **152** of approximately 145 millimeters.

FIG. **5**A illustrates a perspective view of the valve **20** shown in FIG. **2**A. The valve **20** is structured and operates identically as the valve **22** shown in FIG. **2**A. The valve **20** includes outer ports **154**, **156** and an inner port **158**. The outer port **154** is configured to be releasably joined with the conduit **24** shown in FIG. **1**. The outer port **156** is configured to be releasably joined with the conduit **26** shown in FIG. **1**. The inner port **158** is configured to be fixed to the open end **96** of the interior chamber **95** shown in FIG. **2**A for example. The ports of the valve **22** shown in FIG. **2**A respectively join to the conduits **28**, **30** shown in FIG. **1**, and the open end **98** of the interior chamber **95**.

FIG. **5**B illustrates a side view of the valve **20**. FIG. **5**C illustrates a front view of the valve **20**. FIG. **5**D illustrates a top view of the valve **20**.

FIG. **6**A illustrates a front perspective view of the drug compounding skid **10** that is shown in schematic view in FIG. **1**. Components of the drug compounding skid **10**, including the vessels **12**, the sterilization system **14**, and the drug transfer system **16** may be attached to a frame **160** that is configured to stand upon a supporting surface. The cleaning system **18** may also be attached to the frame **160**.

The frame **160** includes a plurality of horizontally extending bars **162** joined to a plurality of vertically extending bars **164**. The horizontally extending bars **162** and vertically extending bars **164** have sufficient strength to support the weight of the vessels **12**, the sterilization system **14**, the drug transfer system **16**, and the cleaning system **18** as desired. Feet **166** are positioned at the lower end of frame legs **165**. The feet **166** are configured to rest upon a supporting surface as desired.

The frame **160** includes vessel holders **168** in the form of prongs that extend outward from the frame **160**. The vessel

holders **168** are shaped to pass in between the plurality of supports **114** that join top plate **110** of the vessel **12** to the bottom plate **112** as shown in FIG. **2**A. The vessel holders **168** contact the two dome shaped end portions **106**, **108** of the vessel container **92** shown in FIG. **2**A to secure the vessel **12** in position. The vessel holders **168** are configured such that the vessel **12** may be slid on and off of the vessel holders **168** when the vessel **12** is joined or released from the frame **160**. The vessel holders **168** bear and transmit the weight of the vessel to the frame **160**. The vessel holders **168** may be shaped to include a tapered edge that matches the angle of the dome shaped end portions **106**, **108**. The shape of the tapered edge provides a secure fit between the vessel **12** and the frame **160**.

FIG. **6**B illustrates a rear view of the frame **160** illustrating the connections between the plurality of horizontally extending bars **162** and the plurality of vertically extending bars **164**.

FIG. **6**C illustrates a front view of the frame **160** illustrating the connections between the plurality of horizontally extending bars **162** and the plurality of vertically extending bars **164**. In addition, the connections between the conduits **24**, **26**, **28**, **30** and the valves of the vessels **12** are also shown in accordance with the schematic shown in FIG. **1**. FIG. **6**D illustrates a rear view of the frame **160**.

FIG. **6**E illustrates a left side view of the frame **160**. The coupler **88** is visible that is used to couple the holding tank **32** (shown in FIG. **1**) to the conduit **47** (shown in FIG. **6**C).

FIG. **6**F illustrates a right side view of the frame **160**. The drain **70** that conveys condensation for removal from the sterilization system **14** (as described in regard to FIG. **1**) is visible. A height **169** of the drain **70** above a supporting surface may preferably be approximately nine inches. A height **170** of the coupler **88** above a supporting surface may preferably be approximately 22 inches. A height **172** of a horizontal support bar **162** above a supporting surface may preferably have a size of approximately 19 inches. A height **174** of a bottom plate **112** (shown in FIG. **2**A) of a vessel **12** may preferably have a size of approximately 36 inches.

FIG. **6**G is a top view of the frame **160**. The skid **10** may preferably have an outermost length **176** of approximately 96 inches. The frame **160** may preferably have a length **178** of approximately 90 inches. The skid **10** may preferably have an outermost width **180** of approximately 39 inches, accounting for the air inlet of the drug transfer system **16**. The frame **160** may preferably have a width **182** of approximately 38 inches.

In operation, the skid **10** allows for sterile transfer of a compounded drug. Components of the skid **10** may be utilized in any manner as desired, however, an exemplary method of operation is as follows. Referring to FIG. **1**, a vessel **12** may be removed from the skid **10** and filled with a drug to be compounded and/or any other substance as desired. Preferably, grinding beads are additionally placed within the vessel **12** to assist to further agitate the drug within the vessel **12**. The drug to be compounded and/or any other substance is preferably inserted into the interior chamber **95** through the first open end **96** and/or the second open end **98** of the interior chamber **95** as shown in FIG. **2**A. The valves **20**, **22** and filters **100**, **102** shown in FIG. **2**A are preferably removed to allow material to be placed within the interior chamber **95**. Once the desired materials are positioned within the interior chamber **95**, the valves **20**, **22** and filters **100**, **102** shown in FIG. **2**A are joined with the first and second open ends **96**, **98** of the interior chamber **95**.

Referring back to FIG. **1**, the vessel **12**, which includes the drug to be compounded, is then joined to the skid **10**. In the embodiment shown in FIG. **1**, up to six vessels **12** may be joined to the skid **10** at one time. The valves **20**, **22** of each vessel **12** are preferably opened. The sterilization system **14** is then activated to direct sterilizing steam to contact and sterilize the interior of the valves **20**, **22** and the interior chambers **95** of the vessels **12** shown in FIG. **2**A. Any drug, grinding bead, or other desired material within the vessel **12** is additionally sterilized. The sterilization system **14** may be operated manually, or may be operated automatically through use of the controller device **90**.

The valves **20**, **22** are closed after the sterilization system **14** sterilizes the interior of the valves **20**, **22**, and the interior chamber **95**. The valves **20**, **22** form a sterile seal of the drug to be compounded within the interior chamber **95**. The valves **20**, **22** are then released from the conduits **24**, **26**, **28**, **30** to allow the vessels **12** to release from the skid **10**. Each vessel **12** is portable and may be physically carried to a separate compounding device.

In an embodiment in which the compounding device is a mill, then each vessel **12** will be placed on the mill such that the outer rims **116**, **118** of the top and bottom plates **110**, **112** (shown in FIG. **2**A) roll upon the mill. While each vessel **12** is on the mill, the valves **20**, **22** remain closed to maintain the sterile seal of the drug within the interior chamber **95**. The vessel **12** may be left on the mill for any desired duration necessary to compound the drug within the vessel **12**. The grinding beads may serve to provide further agitation for the drug that is compounded within the vessel **12**.

After drugs have been compounded in as many vessels **12** as desired, the vessels **12** are joined back onto the skid **10**. The valves **20**, **22** remain closed while the vessels **12** are joined back onto the skid **10**. The vessels **12** are joined to the skid by connecting the conduits **24**, **26**, **28**, **30** back to the respective valves **20**, **22**. Before the valves **20**, **22** are reopened, the sterilization system **14** is activated to direct sterilizing steam to contact and sterilize the exterior portions of the valves **20**, **22**. The exterior portions of the valves **20**, **22** are preferably sterilized to eliminate any microbe or other aseptic materials that may have been encountered on the exterior portions of the valves **20**, **22** while on the compounding device. The exterior portions of the valves **20**, **22** to be sterilized may include the respective outer ports **154**, **156** (shown in FIGS. **5**A-**5**D) of each valve **20**, **22**. The process of sterilizing the exterior portions of the valves **20**, **22** may also sterilize the conduits utilized with the drug transfer system **16**.

Upon the exterior portions of the valves **20**, **22** being sterilized, the drug transfer system **16** is activated to provide an overpressure of air via the air inlet **74**. The air overpressure prevents microbes or other aseptic materials from being drawn into the piping of the drug transfer system **16** from the outside environment of the skid **10**. The valves **20**, **22** are then opened to the sterile environment of the piping of the drug transfer system **16**. The drug transfer system **16** is then activated to direct fluid such that it passes through the first valve **20**, then through the interior chamber **95** (shown in FIG. **2**A) of each of the vessels **12**, and then through each of the second valves **22**. In one embodiment, the fluid used by the drug transfer system **16** may be air from the air inlet **74**. In one embodiment, the fluid used by the drug transfer system **16** may be water or other liquid from the water inlet **72**. In one embodiment, the fluid used by the drug transfer system **16** may include a combination of water or other liquid from the water inlet **72** and air from the air inlet **74**. In this embodiment the liquid may be delivered through the piping of the drug transfer system **16** such that it flows towards each vessel **12**. The liquid may contact the compounded drug to convey it away from the interior chamber **95** (shown in FIG. **2**A) and any grinding beads contained therein. The air from the air inlet **74** may then have its pressure increased to provide a

motive pressure against the liquid, to further drive the liquid away from the interior chamber **95** and the grinding beads.

Upon the compounded drug being directed away from the interior chamber **95** (shown in FIG. **2**A), the air and/or liquid utilized by the drug transfer system **16** conveys the drug down the conduit **47**. Preferably, the compounded drug is delivered to the holding tank **32**. The holding tank **32** serves as a bulk storage unit for all compounded drug delivered from the vessels **12**.

After the compounded drug is passed to the holding tank **32** as desired, the skid **10** may be cleaned. During cleaning, each vessel **12** is removed from the remaining portions of the skid **10**. Each vessel **12**, including the interior chamber **95** and valves **20**, **22** (shown in FIG. **2**A) may be cleaned separate from the skid **10**.

A separate cleaning device, or cleaning skid, may be attached to the skid **10** to clean the respective components and piping. An output of the cleaning device may be joined to the cleaning fluid inlet **84**. An input of the cleaning device may be joined to the skid **10** at the coupler **88**. The holding tank **32** may be decoupled from the coupler **88** and a separate cleaning system return **86** may be joined to the coupler **88** to serve as an input for the cleaning system. The cleaning system **18** may then be operated to clean the conduits of the sterilization system **14** and the drug transfer system **16** as desired.

After the vessels **12** and components of the sterilization system **14** and drug transfer system **16** have been cleaned to the desired degree, then the skid **10** may be prepared to compound another drug.

FIG. **7**A illustrates an exemplary method of operating the skid **10**. The steps shown in FIG. **7**A may be used in lieu or in combination with any other method of operation discussed in this application regarding the skid **10**. Any step may be omitted if effective to produce a desired result. The method may include providing **184** a vessel, which may include any of the vessels **12** discussed in this application. A drug may then be provided **186** in the vessel **12** for compounding.

The vessel **12** may then be joined with the sterilization system **14** and the sterilization system **14** may be operated **188** to sterilize the vessel **12** and the drug contained within the vessel. Upon the vessel **12** and the drug being sterilized, the valves **20**, **22** of the vessel **12** are closed to form a sterile seal of the sterile drug within the interior chamber **95** of the vessel (shown in FIG. **2**A).

The vessel **12** is then removed **190** from the skid **10** and a drug compounding device is utilized. In an embodiment in which the drug compounding device is a mill, the vessel **12** is then placed on the mill.

The mill is operated to compound **192** the sterile drug to produce a sterile compounded drug.

After the sterile compounded drug has been produced, the vessel **12** is then secured **194** to the frame **160** shown in FIGS. **6**A-**6**G.

The sterilization system **14** is operated **196** to direct sterilizing steam to contact and sterilize the first valve **20** and the second valve **22** when the first valve **20** and second valve **22** are closed.

The drug transfer system **16** is then operated **198** to direct fluid through the first valve **20** when the first valve **20** is open, then through the interior chamber **95** (shown in FIG. **2**A), and then through the second valve **22** when it is open, to transfer the sterile compounded drug from the interior chamber **95** to a holding tank **32**.

The cleaning system **18** may then be operated **200** to clean desired conduits of the sterilization system **14** and the drug transfer system **16**.

The steps discussed in regard to FIG. **7**A, or otherwise discussed in this application may be aided through use of the controller device **90**. The controller device **90** may be utilized to automate the operation of components of the sterilization system **14**, the drug transfer system **16**, and/or the cleaning system **18** as desired.

The skid **10** beneficially allows a drug to be compounded and transferred without exposing the drug to an aseptic environment. The skid **10** may enhance the ease of operation to provide a sterile environment for production of drugs.

In one embodiment, steps of a method of using the skid **10** may be used in a process that combines various components to produce a desired compounded drug output. For example, the output from the skid **10** may be combined with various other components to produce a desired product. FIG. **7**B illustrates a process schematic showing output from the skid **10** combined with components from other processing steps. In this embodiment, components **161** may include drugs, grinding beads, water and/or other components for compounding within a vessel **20**. The components **161** may be passed **163** into an interior of the vessels **20**. FIG. **7**B illustrates the grinding beads **167** present within the vessels **20**. The components **161** may be compounded at this stage if desired. In one embodiment, the components **161** may be compounded or milled for approximately 10-30 minutes if desired.

Upon the components **161** being milled for the desired duration, the interior of the vessel **20**, including the components **161** may be sterilized **171**. The sterilization process may occur by the vessels **20** being fixed to the skid **10** and being sterilized in a process identified as step **188** in FIG. **7**A. In the embodiment shown in FIG. **7**B, however, the sterilization process occurs separate from the skid **10**, in an autoclave. The vessel **20** and components **161** may be sterilized for any duration and at any temperature as desired. In one embodiment, the sterilization process may occur for approximately 165-180 minutes at no less than approximately 121.1 degrees Celsius.

The sterilized vessel **20** and components **161** may then be cooled **173** to return to room temperature. The cooled vessel **20** may then be placed upon a compounding device **175** which may comprise a mill as shown in FIG. **7**B. The components **161** within the vessel **20** are then compounded **177** upon the compounding device **175** for any duration as desired. In one embodiment, the compounding process may occur for approximately 168-196 hours. Upon the components **161** being compounded, the vessels **20** may be joined **179** to the skid **10**.

The compounded components **161**, excluding the grinding beads, may then be extracted from the vessels **20**, in a process identified as steps **196** and **198** in FIG. **7**A. The fluid used in the water inlet **72** shown in FIG. **1** may derive from a fluid source **181** that passes through a sterilizing filter **183**. The compounded components **161** may pass through a conduit to a sterile mixing tank **209**.

At a time during, after, or prior to the components **161** from the skid **10** entering the sterile mixing tank **209**, separate components **187**, including drugs, water, and/or other components for use in a drug product may be passed into a sterile mixing tank **191**. The components **187** may be mixed **189** in the tank **191** for any duration or temperature as desired. In one embodiment, the components **187** may be mixed at a temperature between approximately 85 to 90 degrees Celsius.

Upon the components **187** being mixed to the desired degree, the components may be passed and held in bottles **193** where they are stored and cooled for a desired duration. In one embodiment, the components **187** may be cooled to a tem-

perature of approximately 15 to 30 degrees Celsius before they are passed into the bottles. Once in the bottles, the components **187** may be further cooled to approximately 15 degrees Celsius for a time less than approximately 12 hours.

Once the components **187** are cooled in the bottles **193** to the desired degree, they may be pumped **195** via a pump to another sterile mixing tank **197**. The sterile mixing tank **197** may include additional components **199**, which may include drugs, water, and/or other components for use in a drug product. The components **187** may be combined with the additional components **199** within the tank **197** and may be mixed within the tank **197** to a desired degree.

The combined components **187**, **199** may then be pumped **203** via a pump through a pre-filter **205** and sterilizing filter **207**. The components **187**, **199** may pass into the sterile mixing tank **209** in which the components **187**, **199** may be joined with the components **161** delivered from the skid **10**.

The combined components **187**, **199**, **161** may be mixed in the sterile mixing tank **209** to a desired degree. The components **187**, **199**, **161** may then be passed to another processing area for addition of further components and/or other processing, or may be passed to a filling area for a filling process, in which the combined components **187**, **199**, **161** are bottled in a sterile process for end use.

The components **187**, **199**, **161** may be passed into the sterile mixing tank **209** in any order as desired. For example, in one embodiment, the components **187**, **199** may be held in the tank **209** for mixing prior to the components **161** being passed into the tank **209**. The processes shown in FIG. **7**B may be conducted in a sterile environment, including a Class 10,000 area if desired. Any process shown in FIG. **7**B may be modified, omitted, or performed in a different sequence so long as a desired end product results. The processes shown in FIG. **7**B may additionally be used in combination with any skid apparatus discussed in this application or in combination or in lieu of any method or method step discussed in this application to produce a desired end product.

FIG. **8** illustrates a schematic view of an embodiment of a skid apparatus **202** for use to compound drugs. In this embodiment, the skid apparatus **202** includes a plurality of drug compounding tanks **204***a*, **204***b*, **204***c* each configured to retain a drug for compounding therein.

The tanks **204** each include an agitation device **214***a*, **214***b*, **214***c* that is top mounted to the respective tank **204***a*, **204***b*, **204***c*. The agitation devices **214** are configured to agitate a drug retained within the respective tank **204** when the drug retained within the respective tank **204** is being compounded. The agitation devices **214** may include an inline homogenizer, a static mixer, a triblender, and/or a disperser, or any other kind of agitation device as desired.

Each tank **204** may include a respective opening **212***a*, **212***b*, **212***c* that allows a drug or other desired material to be passed into the respective tank **204***a*, **204***b*, **204***c*. Upon delivery of a drug into the respective tank **204***a*, **204***b*, **204***c*, the agitation device **214** serves to agitate the drug in a compounding process. Each tank **204***a*, **204***b*, **204***c* may additionally include a port **216***a*, **216***b*, **216***c* that may receive an additional agitation device for use to agitate the drug contained within the tank **204***a*, **204***b*, **204***c*. The additional agitation device may be used in combination or in lieu of the agitation device **214***a*, **214***b*, **214***c* shown in FIG. **8** as being top mounted upon the respective drug compounding tank **204***a*, **204***b*, **204***c*.

Each tank **204***a*, **204***b*, **204***c* may have a different drug retention capacity than the other tanks. For example, tank **204***a* may have a smaller drug retention capacity than tank **204***b*, which has a smaller drug retention capacity than tank **204***c*. In one embodiment, each tank **204***a*, **204***b*, **204***c* may have a respective volume of 300 liters, 800 liters, and 1200 liters. In other embodiments, the respective volumes may be varied as desired.

Each tank **204** may be loaded on a respective load cell **218***a*, **218***b*, **218***c* that may be capable of sensing the weight of the respective tank **204***a*, **204***b*, **204***c* to determine how much drug or other desired material is contained within the tank **204**.

The skid **202**, similar to the skid **10** shown in FIG. **1** also includes a sterilization system **206**, and a drug transfer system **208**. The skid **202** may also include a cleaning system **210** to allow the skid **202** to be cleaned in place.

The sterilization system **206**, similar to the sterilization system **14** shown in FIG. **1**, includes a sterilizing steam input **220**, valves **222**, **224**, **226**, and conduits **228**, **230**, **232**, **234**, **236**, **238**, **240**, **242**, **244**, **246**, **247**, **248**, **249**, **250**, **266**, **268**, **269**, **270**, **272**. The sterilization system may also include steam traps **251**, thermal sensors **252** and pressure sensors **282**.

Like components of the sterilization system **206** operate similarly as the components of the sterilization system **14** shown in FIG. **1**. For example, the steam input **220** is configured to receive sterilizing steam from an outside source, for example, from a steam generator device. The steam input **220** may include a ball valve that is capable of being opened and closed to selectively allow steam to enter the conduit **228** from the outside source. A steam control valve **222** may also be used to control the rate at which steam enters the conduit **228**.

The conduits **228**, **230**, **232**, **234**, **236**, **238**, **240**, **242**, **244**, **246**, **247**, **248**, **249**, **250**, **266**, **268**, **269**, **270**, **272** may comprise pipes. The pipes may have sufficient strength to withstand the pressure of sterilizing steam being passed therethrough. The pipes may be constructed in a manner that they may be sterilized.

The valves **222**, **224**, **226** are configured to open or close to block the passage of steam or to allow steam to pass therethrough. In one embodiment, the valve **222** may comprise a sanitary control valve. The valves **224** may comprise a two-way directional valve. The valves **226** may comprise a three-way directional valve. In one embodiment, the valves **224**, **226** may each comprise a diaphragm valve. In one embodiment, the valves **224**, **226** may each comprise a pneumatically actuated valve. In one embodiment, the valves **224**, **226** may each comprise an electronically activated valve. In one embodiment, the valves **224**, **226** may each comprise any combination of a diaphragm, pneumatically actuated, or electronically activated valve, as desired.

The thermal sensors **252** of the sterilization system **206** may be capable of detecting a temperature of the sterilizing steam used in the sterilization system **206**. The thermal sensors **252** may be used to indicate when the temperature of the steam is too high or too low to effectively sterilize components of the skid **202**, and may provide an indication to either increase a temperature of the steam input into the steam input **220**, or to change a rate at which steam enters the steam input **220** or passes through the steam control valve **222**.

The pressure sensors **282** of the sterilization system **206** may be capable of detecting a pressure of the sterilizing steam used in the sterilization system **206**. The pressure sensors **282** may be used to indicate when a pressure of the steam is too high or too low to effectively sterilize components of the skid **202**, and may provide an indication to either increase a pressure of the steam input into the steam input **220**, or to change a rate at which steam enters the steam input **220** or passes through the steam control valve **222**.

The sterilization system **206** is configured to pipe sterilizing steam throughout the conduits **228**, **230**, **232**, **234**, **236**, **238**, **240**, **242**, **244**, **246**, **247**, **248**, **249**, **250**, **266**, **268**, **269**, **270**, **272** and through the valves **222**, **224**, **226** to sterilize the conduits **228**, **230**, **232**, **234**, **236**, **238**, **240**, **242**, **244**, **246**, **247**, **248**, **249**, **250**, **266**, **268**, **269**, **270**, **272** and valves **222**, **224**, **226**, and any other desired feature of the skid **202**.

The sterilization system **206** may also be configured to sterilize an interior chamber of each the drug compounding tanks **204***a*, **204***b*, **204***c*. The sterilizing steam passes through valves **224***u*, **224***w*, **224**.*y* and enters the interior chamber of the respective tanks **204***a*, **204***b*, **204***c*. The sterilizing steam then passes through valves **224***ff*, **224***gg*, **224***hh* to exit from the interior chamber.

Upon sterilizing steam passing through the conduits **228**, **230**, **232**, **234**, **236**, **240**, **242**, **244**, **246**, **247**, **248**, **249**, **250**, **266**, **268**, **269**, **270**, **272** and through valves **222**, **224**, **226** of the skid, the steam may reach the steam traps **251**. The steam traps **251** lock the sterilizing steam within the conduits **228**, **230**, **232**, **234**, **236**, **240**, **242**, **244**, **246**, **247**, **248**, **249**, **250**, **266**, **268**, **269**, **270**, **272** of the skid **202**. Condensation produced from the sterilizing steam is collected within the steam traps **251** and is passed to the conduit **238**. The conduit **238** conveys the condensation to a drain **294** for removal from the sterilization system **206**.

The drug transfer system **208** also operates similarly as the drug transfer system **16** shown in FIG. **1**. The drug transfer system **208** includes a fluid inlet, or fluid inlets, which may include a water inlet **254**, and an air inlet **256**. The drug transfer system **208** also includes conduits **248**, **230**, **234**, **266**, **270**, **236**, **249**, **250** and valves **224***c*, **224***d*, **224***e*, **224***f*, **224***g*, **224***h*, **224***i*, **224***j*, **224***k*, **224***l*, **224***m*, **224***n*, **224***o*, **224***p*, **224***q*, **224***r*, **224***s*, **224***u*, **224***w*, **224***y*, **224***ff*, **224***gg*, **224***hh*, **224***ii*, **224***jj*, **224***kk*, **224***ll*, **224***mm*, **224***nn*, **224***pp*, **224***qq*, **224***oo* and may include filters **258**, **260**, flow meters **262**, a regulator **264**, and pressure sensors **282**.

The fluid inlets are configured to allow a fluid such as air or water to enter the inlet from an outside source. For example, the water inlet **254** is configured to receive water, preferably purified water, from an outside water source. The water inlet **254** allows the water to enter the conduit **248**. The air inlet **256** is configured to receive air, preferably oil free air, from an outside air source. The outside air source preferably provides pressurized air, and may comprise an air compressor. The air inlet **256** allows the air to enter the conduit **249**.

The water inlet **254** and air inlet **256** may operate in combination to transfer compounded drugs from the compounding tank **204***a*, **204***b*, **204***c* to the holding tank **280**. The water inlet **254** may allow water to pass through the conduit **248**, through the valves **224***e*, **224***f*, and through liquid filter **258**. The water then passes through valve **224***i* and valves **224***o*, **224***q*, **224***r* to pass into conduit **266**. Water may then pass through valves **224***u*, **224***w*, **224**.*y* to then flush out the drug compounded within the interior chamber. The water may flush out the drug to conduit **236**, which passes through valves **224***pp*, **224***oo* to holding tank **280**.

The air inlet **256** is used to drive the fluid through the drug compounding tanks **204** to allow it to enter the holding tank **280**. The air inlet **256** may allow air to pass through the conduit **249** and through the valve **224***m* so that is passes through conduit **234**, and passes through valves **224***n*, **224***p*, **224***s*. The air drives the water through the conduit **266***a*, **266***b*, **266***c* and conveys it through the respective valves **224***u*, **224***w*, **224***y*, through the interior chamber of the respective holding tanks **204**. The air conveys the water, and the drug through the valves **224***ff*, **224***gg*, **224***hh* and **224***ii*, **224***kk*, **224***mm* and then through the conduit **236**, through the valves **224***pp*, **224***oo* and to the holding tank **280**. The air passes through a filter **260** that scrubs particulate matter and microbes from the air. The regulator **264** may be used to control the air pressure passing through the conduits **249**, **250**, **234**, **266**, **270**, **236**. The pressure sensors **282** may be used to provide a measure of the fluid pressure passing through the conduits, to determine if the pressure should be lowered or raised as desired.

The cleaning system **210** includes a cleaning fluid inlet **274** that allows a cleaning fluid to enter the conduit **246**. The cleaning fluid may comprise water, air, or a caustic fluid such as acid or the like. The cleaning fluid may be provided by a remote cleaning device, such as a cleaning skid. The cleaning fluid may pass through any of the valves **222**, **224**, **226** and conduits **228**, **230**, **232**, **234**, **236**, **238**, **240**, **242**, **244**, **246**, **247**, **248**, **249**, **250**, **266**, **268**, **269**, **270**, **272**. The cleaning fluid may also pass through the steam traps **251**, filters **258**, **260**, and flow meters **262**. A cleaning system return **276** may be coupled to a coupler **278** that is used to couple the holding tank **280** to the conduit **236**. The cleaning system return **276** retrieves the cleaning fluid from the skid device **202** after the cleaning fluid has passed through the desired components of the skid device **202**.

The skid **202** may additionally include a tank-to-tank drug transfer system **284***a*, **284***b* that allows drugs, compounded drugs, or other desired material to be passed between the tanks **204***a*, **204***b*, **204***c*. The drug transfer system **284***a*, **284***b* includes valves **286***a*, **286***b*, **286***c*, **286***d*, pumps **288***a*, **288***b*, and filters **290***a*, **290***b*. The valves **286** may be used to seal off transfer of the desired material between the tanks **204***a*, **204***b*, **204***c*. Upon the valves **286** being opened, the pumps **288** are configured to pump the desired material from tank to tank. The filters **290** are configured to filter the desired material that is passed from tank to tank. A conduit extends from tank to tank to allow the desired material to be passed from tank to tank.

Separate conduits **269***a*, **269***b* may be utilized as part of the sterilization system **206**, to allow sterilizing steam to pass to and sterilize the tank-to-tank drug transfer system **284***a*, **284***b*. The sterilization system may include valves **286** which are opened or closed to allow sterilizing steam to pass therethrough.

In one embodiment, a controller device **292** may be configured to control inlets **254**, **220**, **274**, **256** and/or valves **222**, **224**, **226**, **286** and/or regulator **264**. In addition, the controller device **292** may be configured to receive a temperature reading from temperature sensors **252** and/or a pressure reading from pressure sensors **282**. The controller device **292** may also be configured to receive a rate of flow reading from flow sensors **262**. The controller device **292** may be configured to electrically and automatically open or close one or more of inlets **254**, **220**, **274**, **256** and/or valves **222**, **224**, **226**, **286** and/or regulator **264** to operate any of the sterilization system **206**, the drug transfer system **208**, the cleaning system **210**, or the tank-to-tank drug transfer system **284**. The controller device **292** may comprise an electrical controller device including a processor and memory, and capable of being programmed for operation. In one embodiment, the controller device **292** may comprise a dedicated controller designed to only perform certain tasks related to the sterilization system **206**, the drug transfer system **208**, the cleaning system **210**, or the tank-to-tank drug transfer system **284**. The controller device **292** may be electrically wired to any component of the skid device **202** to provide for desired operation.

In a mode of operation in which the controller device **292** operates the sterilization system **206**, the controller device **292** may open any of the valves **222**, **224**, **226**, **286** to allow

sterilizing steam to sterilize any desired component of the skid device **202**. The controller device **292** may receive a temperature reading from one of the temperature sensors **252** to determine if the temperature of the sterilizing steam is too high or too low, and may open or close one or more valves **222**, **224**, **226**, **286** to allow the temperature to reach a desired point. The controller device may also receive a pressure reading from one of the pressure sensors **282** to determine if the pressure of the sterilizing steam is too high or too low, and may open or close one or more valves **222**, **224**, **226**, **286** to allow the pressure to reach a desired point. In addition, the controller device **292** may operate to vary the temperature or pressure of the sterilizing steam by controlling the remote steam generation device. In one embodiment, the controller device **292** may send a signal for a user to vary the temperature or pressure of the sterilizing steam by controlling the remote steam generation device. In one embodiment, the controller device **292** may send a signal for a user to vary the temperature or pressure of the sterilizing steam by controlling the amount of steam passing through the steam inlet **220** and the steam control valve **222**. The signal may comprise an alarm or the like.

In a mode of operation in which the controller device **292** operates the drug transfer system **208**, the controller device **292** may open any of the valves **224** and operate regulator **264** to allow fluid to convey a compounded drug contained within the tank **204** to the holding tank **280**. The controller device **292** may receive a flow reading from one of the flow sensors **262** to determine if the rate of flow of the fluid, including water and/or air is too high or too low, and may open or close one or more valves **224** or regulator **264** to allow the flow rate to reach a desired point. The controller device may also receive a pressure reading from one of the pressure sensors **282** to determine if the pressure of the fluid is too high or too low, and may open or close one or more valves **224** or regulator **264** to allow the fluid pressure to reach a desired point. In addition, the controller device **292** may operate to vary the flow rate and/or pressure of the fluid by controlling the remote water supply device and/or the air pressure device. In one embodiment, the controller device **292** may send a signal for a user to vary the flow and/or pressure of the fluid by controlling the water supply device and/or the air pressure device. In one embodiment, the controller device **292** may send a signal for a user to vary the flow rate and/or pressure of the air by controlling the amount of air passing through the air inlet **256** and the regulator **264**. The signal may comprise an alarm or the like.

In a mode of operation in which the controller device **292** operates the cleaning system **210**, the controller device **292** may open any of the valves **222**, **224**, **226** to allow a cleaning fluid to clean any desired component of the skid device **202**. The controller device **292** may receive a flow reading from one of the flow sensors **262** to determine if the rate of flow of the cleaning fluid, and may open or close one or more valves **222**, **224**, **226** to allow the flow rate to reach a desired point. In addition, the controller device **292** may operate to vary the flow rate of the cleaning fluid by controlling the remote cleaning device. In one embodiment, the controller device **292** may send a signal for a user to vary the flow of the cleaning fluid by controlling the remote cleaning device. The signal may comprise an alarm or the like.

FIG. **9**A illustrates a front perspective view of the skid apparatus **202** for use to compound drugs. Components of the skid apparatus **202**, including the drug compounding tanks **204**, are shown to be coupled to a frame **293** that stands upon a supporting surface. The frame **293**, similar to the frame **160** shown in FIGS. **6**A-**6**G includes a plurality of horizontal and vertical support bars.

FIG. **9**B illustrates a rear perspective view of the skid apparatus **202** for use to compound drugs.

The skid apparatus **202** beneficially allows drugs to be compounded in any or all of the drug compounding tanks **204**. In an embodiment in which the tank-to-tank drug transfer system **284** is utilized, a first component of a desired drug may be formulated in a first tank, and a second component of a desired drug may be formulated in a second tank. At a desired time, the first component of the desired drug may then be transferred from the first tank to the second tank, and the components may be mixed as desired. The components may be mixed before they are ultimately transferred to the holding tank **280** illustrated schematically in FIG. **8**.

In one embodiment, the controller device **292** may be used to electronically detect connection of an agitation device to a port **216** of the drug compounding tank. The controller device **292** may be able to determine a mode of operation based on the detected agitation device and may be able to operate the agitation device accordingly.

In one embodiment, the controller device **292** may be programmed with a sequence of operation for each agitation device **214** that is connected to the respective drug compounding tank **204***a*, **204***b*, **204***c*. The controller device **292** may operate each agitation device **214** according to the sequence programmed into the controller device **292**. In one embodiment, the controller device **292** may be configured to operate the tank-to-tank drug transfer systems **284** to automatically control transfer of a drug or other desired material from one tank to another tank. The controller device **292** may be configured to automatically control valves **286***a*, **286***b*, **286***c*, **286***d*, and pumps **288***a*, **288***b* to effect transport of a drug or other desired material from tank to tank. The controller device **292** may be capable of automatically operating the agitation device **214** associated with each tank **204**, then passing the drug or other desired material from one tank to another tank, and then passing the material to the holding tank **280** for collection.

The skid **202** beneficially allows for drug compounding and transfer of drugs or materials from tank to tank to expedite the drug compounding process. In an embodiment in which the operation of the skid **202** is automated, the skid **202** may serve as an efficient automated system to pass drugs from one tank to another and to be ultimately collected.

FIG. **10** illustrates a schematic view of a skid **296** for sterile transfer of a compounded drug. The skid **296** operates in a similar manner as the skid **10** shown in FIG. **1**, unless otherwise indicated. Like elements of the skid **296** are marked with a prefix of "10" in relation to the elements of skid **10**. Identical roman numerals across FIGS. **10**A and **10**B are meant to indicate connections between the conduits across these portions of the schematic.

The sterilization system **1014** operates in a similar manner as described in regard to the sterilization system **14** of FIG. **1**. The sterilization system **1014** serves to sterilize any desired component of the skid **296**. The drug transfer system **1016** operates in a similar manner as described in regard to the drug transfer system **16** of FIG. **1**. The drug transfer system **1016** serves to transfer a drug compounded within the vessels **1012** to a holding tank **1032**. The cleaning system **1018** serves to clean any desired component of the skid **296**, with the vessels **1012** preferably removed from the remaining portions of the skid **296** during cleaning.

A difference between the skid **296** shown in FIG. **10** and the skid **10** shown in FIG. **1** is the skid **296** is configured to use

a fluid tank **298** that is used as a component of the drug transfer system **1016**. The fluid tank **298** holds water for use to flush through the vessels **1012** to transport the compounded drug from the vessels **1012** to the holding tank **1032**. The fluid tank **298** may be filled from the water inlet **1072** that passes through valves **1036***e*, **1036***f* and through valve **302***a*. The valve **302***b* may be closed during the filling operation. Air from air inlet **1074** may pass through conduit **1046** and conduit **300** to reach valve **302***c*. Upon the valve **302***c* being opened, the air may pressurize the water in the fluid tank **298**. The valve **302***b* may be opened to cause the pressurized water to pass through conduit **1042** and conduit **1024** and flush drug compounded within the vessel **1012** through conduit **1030** and conduit **1047** to holding tank **1032**.

The valve **1036***h* may additionally be opened to allow pressurized fluid from the fluid tank **298** to pass through conduit **1044**. Upon the valve **302***d* being opened, the fluid passes through the conduit **1047** to flush drug from the vessel **1012** down the conduit **1047**. In one embodiment, the valve **1036***ss* is closed during this operation, causing the pressurized fluid to pass through conduit **1030** and valves **1036***ff*, **1036***hh*, **1036***jj*, **1036***ll*, **1036***nn*, **1036***pp*. The pressurized fluid may enter the vessel **1012** from its lower, or second end, and flush compounded drug away from the grinding beads contained within the vessel **1012**, by fluid passing upward into the vessel and contacting the grinding beads. The valve **1036***ss* may then be opened to cause the fluid within the vessel **1012** to drop downwards and drain from the vessel **1012**. In one embodiment, pressurized fluid passing through conduit **1042** and **1024** may enter the vessel **1012** from its upper, or first end at the same time fluid enters the vessel **1012** from below. Any combination of pressurized fluid entering the vessel **1012** from its lower end or upper end may be used to transfer drug from the vessel **1012** to the holding tank **1032**.

The skid **296** may additionally include valves **304** which allow sterilizing steam or other fluid to pass to and from conduit **1028** without passing through steam traps **1066***e*, **1066***g*, **1066***i*, **1066***k*, **1066***m*, **1066***o*. The valves **304** may comprise a three way directional valve, and may comprise a diaphragm, pneumatically actuated, or electronically activated valve, or any combination therein as desired.

The skid **296** may include a holding tank coupler **306** that allows fluid, including sterilizing steam to pass from the holding tank **1032** and to the drain **1070**. A valve **308** may control flow of the fluid from the holding tank **1032** to the conduit **1048**. A steam trap **310** may prevent sterilizing steam from passing from the holding tank **1032** to the drain **1070**. A thermal sensor **312** may detect a temperature of fluid passing from the holding tank **1032**.

The conduit **1047** may additionally include a pressure sensor **314** to detect a pressure of a fluid passing through conduit **1047**.

The valves **302**, **308** may comprise a two-way directional valve, and may comprise a diaphragm, pneumatically actuated, or electronically activated valve, or any combination therein as desired.

A controller, similar to the controller **90** shown in FIG. **1**, may serve to operate any component of the sterilization system **1014**, the drug transfer system **1016**, and/or the cleaning system **1018** in a manner described in regard to FIG. **1**.

FIGS. **11**A-**11**E illustrate views of the skid **296** shown schematically in FIG. **10**. Like elements of the skid **296** are marked with a prefix of "10" in relation to the elements of skid **10** shown in FIGS. **6**A-**6**G. FIG. **11**A illustrates a front perspective view of the skid frame showing the horizontally extending bars **10162** joined to the plurality of vertically extending bars **10164**. The legs **10165** extend from the horizontally extending bars **10162**. Feet **10166** are positioned at the lower end of frame legs **10165**.

FIG. **11**B illustrates a front view of the skid **296**. The holding tank **1032** is visible positioned adjacent to the coupler **1088** and the holding tank coupler **306**. The holding tank **1032** is configured to be separable from the skid **296**. In the embodiment shown in FIG. **11**B, wheels are shown at the bottom of holding tank **1032** to allow it to be portable relative to the skid **296**. FIG. **11**C illustrates a rear view of the skid **296**. The drain **1070** is visible extending away from the holding tank coupler **306**. The fluid tank **298** is visible positioned at the rear of the skid frame.

FIG. **11**D is a right side view of the skid **296**. The position of the fluid tank **298** is visible relative to the vessels **1012**. FIG. **11**E is a top view of the skid **296**.

The skid **296** embodiment shown in FIGS. **10-11** allows for use of the fluid tank **298**, which beneficially improves control of the fluid used in the fluid transfer system **1014**. The skid **296** embodiment additionally allows for use of the holding tank coupler **306**, which may allow fluid, including sterilizing steam, to be drained from the holding tank **1032** if desired.

The skid devices disclosed throughout this application may be used to compound any form of drug desired. Certain exemplary drugs include steroids, antihistamines, sympathomimetics, beta receptor blockers, parasympathomimetics, parasympatholytics, prostaglandins, non-steroidal anti-inflammatory drugs, topical anesthetics, among others. Such drugs may include a cyclosporine ophthalmic emulsion, a brimonidine tartrate ophthalmic solution, a bimatoprost ophthalmic solution, a ketorolac tromethamine ophthalmic solution, a nedocromil sodium ophthalmic solution, onabotulinumtoxinA, an epinastine HCL ophthalmic solution, alcaftadine ophthalmic solution, a prednisolone acetate ophthalmic suspension, a gatifloxacin ophthalmic solution, and a gatifloxacin ophthalmic solution, among others. The compounded drugs may be offered by brand name, including those offered by Allergan®, Inc., under names such as Refresh®, Restasis®, Alphagan®, Combigan®, Lumigan®, Acular LS®, Acuvail®, Alocril®, Botox®, Elestat®, Lastacaft®, Ozurdex®, Pred Forte®, Zymar®, and Zymaxid®, among others. The description of drugs is intended to be exemplary and non-limiting in nature.

In closing, it is to be understood that although aspects of the present specification are highlighted by referring to specific embodiments, one skilled in the art will readily appreciate that these disclosed embodiments are only illustrative of the principles of the subject matter disclosed herein. Therefore, it should be understood that the disclosed subject matter is in no way limited to a particular methodology, protocol, and/or reagent, etc., described herein. As such, various modifications or changes to or alternative configurations of the disclosed subject matter can be made in accordance with the teachings herein without departing from the spirit of the present specification. Lastly, the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to limit the scope of the present invention, which is defined solely by the claims. Accordingly, the present invention is not limited to that precisely as shown and described.

Certain embodiments of the present invention are described herein, including the best mode known to the inventors for carrying out the invention. Of course, variations on these described embodiments will become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventor expects skilled artisans to employ such variations as appropriate, and the inventors intend for the present invention to be practiced otherwise than specifically described herein. Accordingly, this invention includes all

modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described embodiments in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

Groupings of alternative embodiments, elements, or steps of the present invention are not to be construed as limitations. Each group member may be referred to and claimed individually or in any combination with other group members disclosed herein. It is anticipated that one or more members of a group may be included in, or deleted from, a group for reasons of convenience and/or patentability. When any such inclusion or deletion occurs, the specification is deemed to contain the group as modified thus fulfilling the written description of all Markush groups used in the appended claims.

Unless otherwise indicated, all numbers expressing a characteristic, item, quantity, parameter, property, term, and so forth used in the present specification and claims are to be understood as being modified in all instances by the term "about." As used herein, the term "about" means that the characteristic, item, quantity, parameter, property, or term so qualified encompasses a range of plus or minus ten percent above and below the value of the stated characteristic, item, quantity, parameter, property, or term. Accordingly, unless indicated to the contrary, the numerical parameters set forth in the specification and attached claims are approximations that may vary. In addition, each length, width, height, or other dimension disclosed in this application may be varied as desired to produce an equivalent result. At the very least, and not as an attempt to limit the application of the doctrine of equivalents to the scope of the claims, each numerical indication should at least be construed in light of the number of reported significant digits and by applying ordinary rounding techniques. Notwithstanding that the numerical ranges and values setting forth the broad scope of the invention are approximations, the numerical ranges and values set forth in the specific examples are reported as precisely as possible. Any numerical range or value, however, inherently contains certain errors necessarily resulting from the standard deviation found in their respective testing measurements. Recitation of numerical ranges of values herein is merely intended to serve as a shorthand method of referring individually to each separate numerical value falling within the range. Unless otherwise indicated herein, each individual value of a numerical range is incorporated into the present specification as if it were individually recited herein.

The terms "a," "an," "the" and similar referents used in the context of describing the present invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as") provided herein is intended merely to better illuminate the present invention and does not pose a limitation on the scope of the invention otherwise claimed. No language in the present specification should be construed as indicating any non-claimed element essential to the practice of the invention.

Specific embodiments disclosed herein may be further limited in the claims using consisting of or consisting essentially of language. When used in the claims, whether as filed or added per amendment, the transition term "consisting of" excludes any element, step, or ingredient not specified in the claims. The transition term "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic(s). Embodiments of the present invention so claimed are inherently or expressly described and enabled herein.

All patents, patent publications, and other publications referenced and identified in the present specification are individually and expressly incorporated herein by reference in their entirety for the purpose of describing and disclosing, for example, the compositions and methodologies described in such publications that might be used in connection with the present invention. These publications are provided solely for their disclosure prior to the filing date of the present application. Nothing in this regard should be construed as an admission that the inventors are not entitled to antedate such disclosure by virtue of prior invention or for any other reason. All statements as to the date or representation as to the contents of these documents is based on the information available to the applicants and does not constitute any admission as to the correctness of the dates or contents of these documents.

What is claimed is:

1. A skid apparatus for sterile transfer of a compounded drug comprising:

a frame configured to stand upon a supporting surface;

a vessel having an interior chamber and an outer surface with a first open end and a second open end, and configured to retain a drug that is compounded within the interior chamber, and having a first valve at the first open end and a second valve at the second open end that are configured to form a sterile seal of the drug compounded within the interior chamber, the vessel configured to be releasably retained by the frame and to be used with a drug compounding device that compounds the drug within the interior chamber when the vessel is released from the frame;

a sterilization system coupled to the frame and configured to direct sterilizing steam to contact and sterilize the first valve and the second valve when the vessel is retained by the frame; and

a drug transfer system coupled to the frame and configured to direct fluid such that the fluid passes through the first valve, then through the interior chamber, and then through the second valve to transfer the drug that is compounded within the interior chamber to a holding tank when the vessel is retained by the frame.

2. The apparatus of claim **1**, wherein the vessel includes a plurality of grinding beads in the interior chamber that are configured to grind the drug when it is being compounded.

3. The apparatus of claim **2**, wherein the vessel includes a filter configured to prevent the grinding beads from exiting the vessel when the fluid passes through the first valve, then through the interior chamber, and then through the second valve.

4. The apparatus of claim **1**, further comprising a controller device configured to automatically operate the sterilization system and the drug transfer system.

5. The apparatus of claim **4**, wherein the controller device is configured to automatically open at least one valve to allow the sterilizing steam to contact and sterilize the first valve and the second valve.

6. The apparatus of claim **4**, wherein the controller device is configured to automatically open at least one valve to allow the fluid to pass through the first valve, then through the interior chamber, and through the second valve.

7. The apparatus of claim **1**, further comprising a cleaning system configured to deliver fluid through pipes of the sterilization system and the drug transfer system to clean the pipes.

8. The apparatus of claim 1, wherein the first valve is configured to form a sterile bond with a conduit of the sterilization system.

9. The apparatus of claim 8, wherein the first valve is configured to either be open or closed when the first valve forms the sterile bond with the conduit of the sterilization system.

10. The apparatus of claim 1, wherein the vessel is a first vessel; and

the apparatus further comprises a second vessel having an interior chamber and an outer surface with a first open end and a second open end, and configured to retain a drug that is compounded within the interior chamber of the second vessel, and having a first valve at the first open end and a second valve at the second open end of the second vessel that are configured to form a sterile seal of the drug compounded within the interior chamber of the second vessel, the second vessel configured to be releasably retained by the frame and to be used with the drug compounding device that compounds the drug within the interior chamber of the second vessel when the second vessel is released from the frame.

11. The apparatus of claim 10, wherein the drug transfer system includes a pipe configured to allow the drug that is compounded within the interior chamber of the first vessel and the drug that is compounded within the interior chamber of the second vessel to transfer to the holding tank when the first vessel and the second vessel are both retained by the frame.

12. The apparatus of claim 1, wherein the frame is configured to releasably retain the vessel such that the first open end is substantially above the second open end when the vessel is retained by the frame.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 9,314,404 B2
APPLICATION NO. : 13/848586
DATED : April 19, 2016
INVENTOR(S) : Jose Gonzalez-Miranda et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the specification,

In column 3, line 43, delete "invention" and insert -- invention; --, therefor.

In column 8, line 25, delete "32" and insert -- 32. --, therefor.

In column 17, line 11, delete "224.y" and insert -- 224y --, therefor.

In column 17, line 53, delete "224.y" and insert -- 224y --, therefor.

Signed and Sealed this
Twelfth Day of July, 2016

Michelle K. Lee

Michelle K. Lee
Director of the United States Patent and Trademark Office